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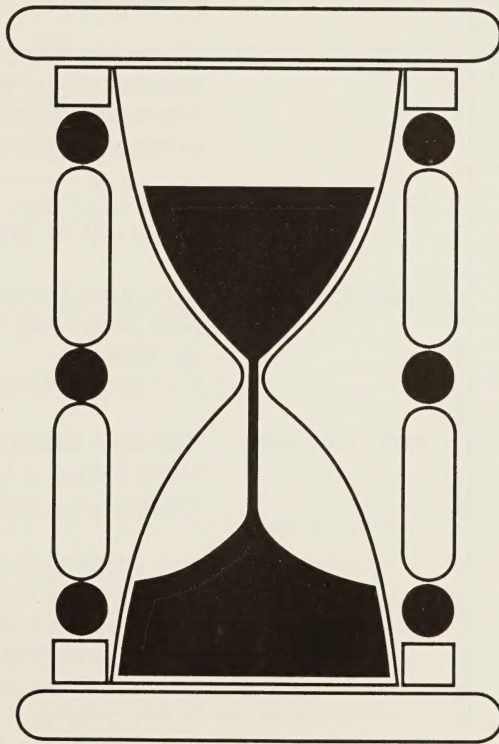
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The Maryland Pharmacist

VOL. 70

January, 1994

NO. 1



*Update on Hypnotics
and Sedatives*



Looking to the Future

The 1994 Mid-Year
Educational Meeting

February 6, 1994

Maryland Pharmacists
Association

Tentative Program

- | | |
|------------------|--|
| 8:00 - 8:45 am | Registration and Continental Breakfast
<i>Atrium</i> |
| 8:45 - 9:00 am | President's Welcome
Howard R. Schiff, P.D.
MPhA President
<i>Chesapeake Ballroom</i> |
| 9:00 - 10:00 am | Continuing Education Seminar
The Future of Pharmacy in the
American Health Care System
<i>Chesapeake Ballroom</i> |
| 10:00 am - 12:00 | Continuing Education Seminar
Implementing Pharmaceutical Care
Practical Applications
<i>Chesapeake Ballroom</i> |
| 12:00 - 1:00 pm | Buffet Luncheon
<i>Atrium and Windjammer</i> |
| 1:00 - 4:00 pm | Continuing Education Seminar
New Drugs and Drug Therapies
for 1994
<i>Chesapeake Ballroom</i> |
| 4:00 - 5:00 pm | Business Session
MPhA House of Delegates
Speaker Alisa Billington presiding |
1. Role Call of Delegates
 2. Legislative Briefing
 3. Nominations for MPhA Elections
 4. Nominations for Maryland Board of Pharmacy
 5. Briefing: UMAB School of Pharmacy Non-Traditional Pharm.D. Program
 6. Other Business

**Complete program information will be
mailed to all pharmacists this month!**

The Maryland Pharmacist

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650 West Lombard Street, Baltimore, Maryland 21201-1572

January 1994

Volume 70

Number 1

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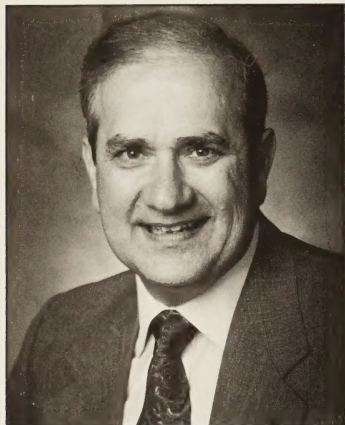
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President's Commentary

Howard Schiff, P.D.



At the beginning of a new year, it's common to reflect on the past year and see how we have changed. Recently, while rummaging through some old pictures and souvenirs, I came across an *American Druggist* from November 13, 1972. The eight cent first class postage stamp honoring pharmacy had just been issued and was shown on page two. Tedral Elixir was advertised (does anyone still dispense Tedral?) at \$4.25 per pint. Darvon N and Darvon N ASA were advertised in new unit-of-use bottles of 30. A list of the top 200 prescription products included such favorites as Achrocidine, Bendectin, Equagesic, Nembutal, Orinase, Preludin and Vasodilan. Aside from the memorabilia, it was interesting to see which issues were important to the pharmacy community at that time, and consider whether they had been resolved over the last 21 years.

Safety packaging was just coming into use. Then, they applied only to aspirin, methyl salicylate and controlled drugs. The FDA had set a deadline of January 22, 1973 for their use. Compulsory continuing education and patient profiles were hot issues in the letters to the editor. The New Jersey Board of Pharmacy, headed by University of Maryland graduate Paul Pumpian, was issuing new rules for the handling of prescriptions in nursing homes including some that are today an accepted part of federal policy.

In an article titled "How Big A 'Third Party' Professional Fee Are You Getting," Maryland pharmacists were listed as receiving \$1.75 on Medicaid, \$1.95 from Blue Cross and \$2.10-\$2.15 from PCS. These numbers seem kind of familiar to anyone dealing with third parties today. I wonder if today's post office could survive with the eight cent postage on first class mail that was in effect in 1972.

What I hope is not a harbinger of things to come was reported in a column called "Washington Insider." We were informed that drug benefits for chronic conditions and diseases had been eliminated from Medicare by a Senate-House conference because they would be too costly. If prescription coverage had been included, the current health care reform package from President Clinton would be radically different. Mail order and super discounts on pharmaceuticals are direct results of drugs being excluded from Medicare. If things had been different in 1972, the issue of elderly patients choosing between food and medications would never have arisen.

Can we point to progress over the last two decades? Yes, there have definitely been significant professional advances. Today's pharmacist's have a higher profile; we are more involved in patient care and are more politically aware. We fill more prescriptions with better drugs from more therapeutic usage categories and help provide a longer and better quality of life than ever before.

Economically, however, we are fighting for survival as never before. No other profession or business is expected to provide up-to-date services at 1972 compensation levels. In truth, the world has changed drastically since the early 70's and survive, we also must change.

R

Patient Counseling on Hypnotics

General Guidelines, Benzodiazepines, and The Next Generation

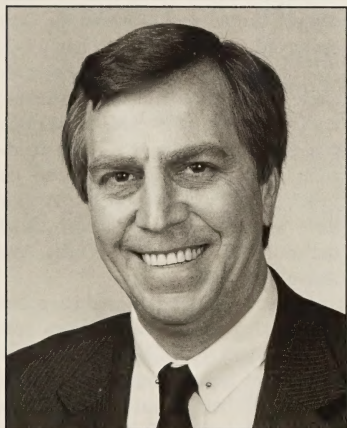
Thomas A. Gossel, R.Ph., Ph.D., Associate Dean, Ohio Northern University

J. Richard Wuest, R.Ph., Pharm.D., Professor of Pharmacy, University of Cincinnati



While insomnia and daytime drowsiness are two of the most common complaints, reported in approximately 32.5 million Americans, studies suggest that a significant number of serious insomniacs remain untreated. It is becoming increasingly clear that poor night-time sleep and resulting next-day drowsiness are causes of diminished ability to concentrate, memory impairment, failure to accomplish daily tasks, and interpersonal difficulties. They are also a major contributor to work-related accidents and lost productivity, as well as traffic accidents. The U.S. Department of Transportation reports that 200,000 automobile accidents are caused each year by drivers who fall asleep at the wheel.

The ideal hypnotic drug should induce sleep soon after ingestion and sustain it for the expected duration without episodes of nocturnal or early morning awakenings. Its action should not be so long that it causes morning hangover and impaired daytime performance. Patients should not develop tolerance or dependence to it when used on consecutive evenings. It should not alter the patient's natural sleep patterns or induce next-day drowsiness, rebound insomnia or amnesia. It should possess a wide margin of safety. The ideal hypnotic should make abnormal sleep normal, while not making the sleep of a normal sleeper abnormal. When the drug is discontinued, the patient should not experience withdrawal symptoms. Moreover, it should not cause significant drug-drug or drug-food interactions.



The Consensus Development Conference on Drugs and Insomnia in 1983 concluded that benzodiazepine derivatives are closest to possessing the properties of the ideal hypnotic drug. Conference members reached their consensus after considering all of the then-marketed hypnotics including barbiturates, nonbarbiturates and benzodiazepines. However, conference members also recognized that benzodiazepine derivative hypnotics fell short of being ideal because of adverse effects associated with their use, including rebound insomnia, anterograde amnesia, next-day drowsiness and dependence. They affirmed an important point, that "...the search for new and better treatments for insomnia should continue."

Hypnotics do not cure insomnia; they provide symptomatic relief. When they are employed, they should be used as adjunctive treatment for transient to short-term insomnia as part of a therapeutic program that consists of patient education about the basic disorder and non-pharmacologic treatment.

History

Herbal remedies and other potions have been used throughout history to promote sleep. Chloral hydrate and bromide mixtures were popular in the late-1890's. Barbiturates appeared near the turn of the century and remained hypnotics of choice until the late-1960's. Today, the risk of abuse and deaths due to overdose from barbiturates has discouraged their use

as hypnotics.

The benzodiazepines were released during the 1960's and marked a new beginning for safety and specificity of action. Deaths from hypnotic drug overdose declined dramatically. The benzodiazepine derivatives proved to be more CNS-specific in their action than barbiturates which cause a higher level of lethal respiratory depression.

Properties of an Ideal Hypnotic

The ideal hypnotic drug should induce sleep soon after ingestion and sustain it for the expected duration without producing episodes of nocturnal or early morning awakenings. Its duration of action should be short enough that it does not cause morning hangover and impaired daytime performance. It should not induce tolerance or dependence when used for several consecutive nights. It should not alter the patient's natural sleep patterns or cause next-day drowsiness, rebound insomnia, amnesia, or withdrawal symptoms on cessation of therapy. It should not cause significant interactions with other drugs or food.

An important consideration that helps distinguish between anxiolytic (sedative) and hypnotic uses or CNS-depressant drugs is their rate of absorption. An anxiolytic drug, for example, should not reach excessively high plasma concentration too quickly and cause hypnotic action. In contrast, a hypnotic drug should be rapidly absorbed so that it will have a relatively prompt onset of action.

The time required for elimination from the body is another important factor for hypnotic drug action. This is usually expressed in terms of elimination half-life ($t_{1/2}$), which is the time it takes from the point of peak plasma concentration until one-half of that amount remains. Elimination half-life should not be confused with duration of action. A long biological half-life does not always correlate with a long duration of action, and a short half-life does not necessarily

Representative Barbiturate and Nonbarbiturate Hypnotic Drugs

<u>Class</u>	<u>Generic/Trade Names</u>	<u>Dosage Range</u>
<i>Barbiturates</i>		
	Pentobarbital/Nembutal	100-200 mg
	Secobarbital/Seconal	100-200 mg
<i>Nonbarbiturates</i>		
	Chloral Hydrate	500 mg
	Ethchlorvynol/Placidyl	500 mg
	Glutethimide	250-500 mg
	Paraldehyde	10-30 ml
<i>Antihistamines</i>		
	Diphenhydramine	25-100 mg
	Doxylamine/Unisom	25-100 mg

mean the drug has a short duration of action.

Hypnotics differ from one another in their half-lives. Since a sleep time of 7 to 8 hours is sufficient for most people, a hypnotic with a half-life that exceeds 7 hours may remain at high enough concentration in the body throughout the morning, thereby producing hangover.

A hypnotic with a half-life of 3 to 4 hours is satisfactory for people who have difficulty falling asleep. For those who cannot remain asleep or awaken prematurely, a drug with a half-life of 5 to 7 hours is more appropriate.

The accumulation factor is another reason why the elimination half-life should be carefully considered. When ingested over successive nights, a hypnotic with a long half-life can remain at high levels in the plasma and accumulate in the body. This accumulated drug can suppress alertness and psychomotor function during waking hours the next day.

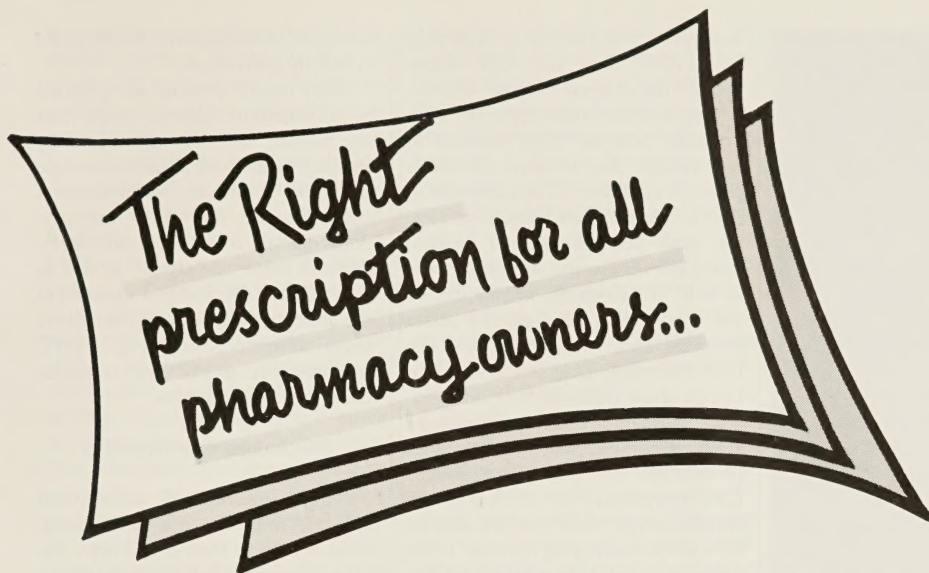
Hypnotic Drugs

Barbiturate and Nonbarbiturate Hypnotics. At present, most barbiturates and nonbarbiturate hypnotics (Table 1) are rarely prescribed. There are few, if any, sound reasons to use them to treat

insomnia, with the possible exception of patients who do not respond to the newer, safer hypnotics. Their risks for causing tolerance, addiction and death by overdose are considerably greater than that with benzodiazepine derivatives which have replaced them in therapy. Benzodiazepines are safer and less prone to drug dependence.

There is a newer class of nonbenzodiazepine hypnotics, the imidazopyridines. The first of these drugs, zolpidem (Ambien®), was approved for marketing in late 1992. Another member of the class, zolcclone, is in phase III clinical studies, and several others are at various stages of development. These imidazopyridine derivatives seem to be nearly ideal as hypnotics in that they have a rapid onset of action, short duration of action, and very low abuse potential.

Once the standard for inducing and maintaining sleep, barbiturates lost popularity as a result of their narrow margin of safety and high risk of toxicity. Their abuse potential is a problem as is the suppression of delta and REM sleep. Barbiturates cause REM rebound following abrupt discontinuation. Tolerance occurs, leading to decreased efficacy in inducing and maintaining sleep over 14 consecutive nights of use at the same dosage. Barbiturates are



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This continuing education article will provide the reader with up to three hours of continuing education credit. To earn credit, turn to page 23 and complete the form and quiz on that page.

Learning Objectives

At the conclusion of this lesson, the participant should be able to:

- Choose correct information about the pharmacology and toxicology of hypnotic drugs discussed in this lesson.
- Select important pharmacokinetic principles about these drugs.
- Select means by which elderly individuals respond to hypnotics differently than younger adults.
- Identify properties of the ideal hypnotic drugs.
- Choose important information to convey to persons using hypnotic drugs to help overcome sleep disorders.
- Select the pharmacologic action of benzodiazepines.
- Differentiate between commercially available benzodiazepine hypnotic drugs.
- Identify adverse effects caused by benzodiazepine.
- Demonstrate knowledge of information to use in counseling patients taking benzodiazepines.
- Identify the pharmacologic, pharmacokinetic, and toxicologic actions of zolpidem.
- Demonstrate knowledge of appropriate information to pass along to patients when counseling on hypnotic use.

implicated in a number of drug-drug interactions since they can induce hepatic microsomal enzyme systems.

The nonbarbiturate hypnotics were originally believed to be superior to barbiturates due to their dissimilar chemical structure. With exception of chloral hydrate, they possess many of the same disadvantages of barbiturates, and have some additional ones as well. To illustrate, methaqualone was shown to have a greater abuse potential than barbiturates, and the DEA eventually placed it in schedule I (high abuse potential with no legitimate therapeutic use). It is no longer available commercially. In overdose, glutethimide not only caused intense CNS depression, but also has strong anticholinergic toxicity which may be even more challenging to treat. It has been placed in schedule II by the DEA. The other members of this group have been replaced by benzodiazepine derivatives.

Chloral Hydrate. The only nonbarbiturate hypnotic that is still prescribed to any extent is chloral hydrate. Its hypnotic action appears within 30 minutes. Chloral hydrate is converted by hepatic alcohol dehydrogenase to trichloroethanol, an active metabolite with a half-life of 4 to 14 hours.

Chloral hydrate may potentiate the activity of warfarin and other drugs with high plasma protein binding affinity by competing for their binding sites. It can cause intense gastrointestinal irritation in some individuals. Its effects are potentiated by alcohol, and this forms the basis for the legendary knockout drops of a "Mickey Finn."

Antihistamines.

Diphenhydramine and doxylamine are ingredients of OTC sleep aid products. The drugs are useful because of their sedative side effects.

The sleep inducing effect of 50 mg diphenhydramine is reported to be equivalent to 60 mg of pentobarbital. Increasing its dose does not result in increased effectiveness. However, increasing the dose does enhance anticholinergic side effects which, in

turn, can be particularly bothersome to elderly individuals.

Many elderly persons are plagued by constipation, blurred vision and dry mouth, and they are especially sensitive to the central anticholinergic effects of confusion, disorientation and impaired short-term memory. Consequently, consumers should be aware of these side effects, as well as the potential for additive depressant and anticholinergic effects from other antihistamine-containing OTC products such as hay fever remedies and cough suppressants.

Precautions with Hypnotics

Drug dependence with sedative and hypnotic drug use has been recognized for more than a century. Patients at greatest risk are those taking a short-acting barbiturate such as pentobarbital, or a short-acting nonbarbiturate hypnotic, such as glutethimide.

The term "dependence" is rather vague and subjective, and its interpretation is left to the discretion of the Director of the Drug Enforcement Agency. It means that the drug has the potential for abuse when used for nonmedical purposes, and that there is an overwhelming physical and physiologic desire for the drug. Dependence also means that the person will experience withdrawal symptoms when the drug is discontinued.

Tolerance develops when the person takes larger doses to get the same results experienced with initial therapy. Users develop an overwhelming desire to continue taking the drug and to obtain it by whatever means needed. They acquire a physiologic need for the effects the drug exerts in the brain.

Sudden cessation of hypnotics in dependent persons leads to withdrawal symptoms such as anxiety, physical discomfort, insomnia, abdominal cramps, nausea, vomiting, diarrhea, profuse sweating, tremors, hallucinations, and seizures.

Physicians and patients may believe

that all hypnotic drugs should be avoided because of the dangers of developing dependence. To place this concept into proper perspective, if hypnotic drugs are used appropriately (i.e., for short periods and at low doses), the risk for dependence is low.

Another concern with the use of hypnotics, originally seen with barbiturates, is *drug-withdrawal insomnia*. This condition is associated with abrupt discontinuation after long-term use. Following chronic REM suppression induced by barbiturates, abrupt cessation leads to REM rebound, amounting to as much as 40 percent of total sleep time. This phenomenon is accompanied by extremely intense and horrifying dreams, and generally disrupted sleep. It can happen in patients taking benzodiazepines, but less often than with barbiturates.

Drug withdrawal insomnia can be modified by gradually tapering the dosage, or switching to an equivalent amount of a longer-acting hypnotic. Educating patients about the possibility of temporary increased

dreaming and decreased quality of sleep should help them better tolerate discontinuation of their hypnotic.

Rebound insomnia is associated with abrupt discontinuation of short-acting hypnotic. This is characterized by worsening of the quality of sleep, more than it was before the patient started taking the drug. The incidence of the phenomenon is unclear and rebound insomnia rarely lasts beyond a single night. Gradual tapering of the drug, rather than abrupt withdrawal, may lessen the severity of symptoms.

Elderly persons should be especially cautious about taking hypnotic drugs. Elderly individuals as a group tend to eliminate drugs more slowly than younger adults. They may be more sensitive to a given blood concentration, and are more prone to develop cognitive and motor impairment with usual adult doses of hypnotic drugs.

The elderly are more likely to be taking additional drugs that can interfere with the normal pharmacodynamics and pharmacokinetics of

hypnotic drugs. Ataxia and memory loss may not be detected for several weeks following the onset of therapy. For these, and other reasons, hypnotic therapy must be closely monitored in elderly individuals.

General Guidelines

Thorough assessment of the patient including identification of underlying causative factors should be undertaken before treating insomnia. Once the decision is reached to treat insomnia with hypnotics, several parameters play a major role in choosing the most appropriate drug. These include the onset of action and duration of effect. Consideration is given to single and multiple dosing, and the patient's past history of response to other medications.

The risk of falls and fractures increases in patients who take hypnotic agents. Hypnotics raise the arousal threshold which is advantageous in overcoming insomnia. However, this can be a disadvantage if patients fail to respond to fire alarms, a crying



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infant, pain, a full bladder, etc. Hypnotics should be avoided in patients who use alcohol or other CNS depressants, pregnant women, persons with sleep apnea, and others for whom alert performance is mandatory (e.g. firemen, pilots, surgeons, pharmacists).

No hypnotic is ideal for every patient and not all insomniacs should be treated with hypnotics. Hypnotics should only be used to treat transient, short-term insomnia, or for a brief period of time in chronic insomnia while a physician is determining its cause. Hypnotic-induced sleep is unnatural in some respects; thus, a measure of efficacy is to determine whether daytime performance is compromised the day after the drug is used.

The philosophy of whether or not to use hypnotics in chronic insomnia is complex. There are few data regarding their efficacy and safety when taken for periods longer than several weeks. More over, there is no conclusive evidence to substantiate that chronic insomniacs also suffer from an underlying psychiatric condition or that they have a drug or alcohol dependence, sleep apnea, or delayed sleep phase syndrome.

Treatment specific for the underlying disorder and non-pharmacologic approaches should be tried first. If medical and psychiatric disorders have been ruled out and nonpharmacologic approaches have failed to bring relief, referral to a sleep-disorders center is appropriate. If a thorough sleep evaluation has been undertaken and a hypnotic has been prescribed for treating chronic insomnia, the patient should be assessed frequently for improvement in both sleep and daytime functioning. This will help assure that the therapeutic effect of the drug is being maintained at the prescribed dose and that the patient is in compliance with recommended dosing frequency. The reason for this is that chronic use of hypnotics carries an enhanced risk for dependence, tolerance with resulting escalation of dosage, and difficult

withdrawal from the medication.

Patients should be provided information about the importance of short-term use of hypnotics, the possibility of morning hangover resulting in daytime sedation and impairment, problems associated with concomitant use with other CNS depressants, and a listing of the risks of tolerance and dependence if the medication is used for too long and/or at excessively high doses. When hypnotics are prescribed for use over extended periods of time, it may be helpful to skip a dose or two once in awhile (e.g. every Friday, or every Friday and Saturday). This concept of drug holidays allows the patient to assess whether the drug is still needed. It can also lessen development of tolerance.

Use of Prescribed Hypnotic Drugs

Period of <u>Drug Use</u>	Percent of Total <u>Users of Hypnotics</u>
1-2 days	54
2-13 days	20
2 or 3 weeks	4
1-3 months	6
4-11 months	6
> 12 months	10

Arch Gen Psychiatry 42:225, 1985

Table 2

While some believe that hypnotics are misused, most studies show that the majority of patients on a hypnotic medication take it as instructed and not for excessive periods of time. Table 2 summarizes the patterns of prescription hypnotic drug use. In this study, 74 percent of patients took their medication for less than two weeks of consecutive use. Fifty-four percent took hypnotic medication for only one or two consecutive nights.

General Patient Advice

- Why compliance is important: If you have been taking the medicine for long periods of time, do *not* stop taking your medicine without consulting your doctor. It may be best to gradually reduce the dosage.
- Take this medicine with one-half to one full glass of water or other liquid at least 15 minutes before going to bed to assure that it will be effective by bedtime. The dose can be followed by a light snack.
- The CNS depressant activity of this medication is potentiated by alcohol. Do not drink alcoholic beverages while taking this medication.
- Some people experience disturbed sleep for 1 or 2 days after discontinuing this medication. This should go away. If it continues, contact your doctor.
- This medicine may cause drowsiness (hangover) in the morning. Make sure you are alert before driving.

Benzodiazepines

Benzodiazepine derivatives are, at present, close to the ideal hypnotic, although the imidazopyridines may soon emerge as superior. In 1983, the Consensus Development Conference on Drugs and Insomnia was held at the National Institute of Mental Health. Its conclusions, published shortly thereafter (*JAMA* 251:2410, 1984), listed three significant outcomes: (1) hypnotics should be used, if at all, primarily in the treatment of short-term insomnia, such as situational (e.g. stress), jet lag, and work-shift change; (2) when a drug is indicated, a benzodiazepine is generally the treatment of choice; and (3) selection of the specific agent should be based on its pharmacodynamic and pharmacokinetic characteristics selected to match the individual patient and situation.



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Mechanism of Action

There are four major neurotransmitters involved in sleep physiology: acetylcholine, dopamine, gamma aminobutyric acid (GABA) and serotonin. Of these, GABA is an extremely important inhibitory neurotransmitter in the brain stem and foreparts of the higher centers of the brain. When released from its storage areas, GABA reacts with its receptors on central neurons, thereby reducing passage of nerve impulses upward to the brain's higher centers.

Receptor sites are chemical configurations on cell membranes that allow natural neurotransmitters to combine and react to either increase or decrease the activity (inhibition) in the brain which allows for sleep. Physiologically, GABA enhances entry of chloride ions into neurons. This hyperpolarizes them, raising their threshold for firing and prevents impulses that would otherwise move upward to the cerebral cortex. With reduced stimulation from the environment, consciousness is lessened, the individual relaxes, and sleep follows.

Benzodiazepines induce hypnotic action due to their ability to bind with specific chemical configurations (receptor sites) on neurons and, by doing so, enhance the activity of GABA. This, in turn, promotes and maintains sleep.

To date, three different "benzodiazepine" receptor sites have been identified. These are referred to as omega-1 (BZD-1, BZ-1), omega-2 (BZD-2, BZ-2) and omega-3 (BZD-3, BZ-3) sites.

The precise physiological difference between the omega receptor sites is not fully known, but the omega-1 type appears to be the most important for inducing and maintaining sleep. Omega-2 and omega-3 subtype receptors are more closely associated with alternative benzodiazepine activities (i.e., anticonvulsant, muscle relaxation), adverse effects and addiction potential.

Most benzodiazepines do not differentiate between these three

Classification of Benzodiazepine Derivative Hypnotic Drugs

Generic/Trade Name	Time to Peak Plasma Levels	Half-Life (Hours)	Dosage Range
Estazolam/ProSom	2 hours	10-24	1-2 mg
Flurazepam/Dalmane	0.5-1 hours	47-100	15-30 mg
Quazepam/Doral	2 hours	39	7.5-15 mg
Temazepam/Restoril	2-4 hours	9.5-12.4	7.5-30 mg
Triazolam/Halcion	0.5-2 hours	1.5-5.5	0.125-0.25

Table 2

receptor sites and, consequently, bind with all three types to differing degrees. Many experts believe that the ideal hypnotic will bind only with omega-1 receptors. In fact, one of the currently available benzodiazepines, quazepam, reportedly binds specifically with omega-1 receptors, but its metabolites bind with the other two as well.

Benzodiazepines as a group are similar to each other, but they do differ in several important ways. They possess varying degrees of hypnotic, anxiolytic (anti-anxiety), anticonvulsant and muscle relaxant activity. Differences among the drugs appear to be due to varying affinities for the above described receptors sites. While they exert little effect on other organ systems, benzodiazepine hypnotics can produce different levels of CNS depression.

Other differences among benzodiazepines include the rate of absorption, level of protein binding, elimination half-life, and metabolic profile. These differences can be especially significant in geriatric patients.

Benzodiazepines have been studied extensively for the full range of their potential usefulness. Table 3 classifies benzodiazepine derivative hypnotic drugs.

Several other benzodiazepines are included in an intermediate zone in that, while they are used mainly to treat anxiety, they can also be used to induce sleep when anxiety is a factor. The group includes alprazolam (Xanax®), lorazepam (e.g., Ativan®) and oxazepam (e.g., Serax®).

Choosing a Benzodiazepine Hypnotic

The choice of a particular hypnotic benzodiazepine is based on a number of factors including the patient's sleep complaint (i.e., can't get to sleep or can't stay asleep), the patient's age and physical condition, the drug's kinetics and the type of insomnia being treated: transient, short-term or chronic.

Transient insomnia is best treated with a low-dose, rapidly metabolized benzodiazepine that has a short half-life. Benzodiazepines can be used in short-term insomnia as an adjunct to better sleep hygiene. Their use should be limited and intermittent. The need for patients to understand this is extremely important.

Benzodiazepines can also be used for patients with chronic insomnia, but they should be reserved for the period during which the physician is determining the underlying cause. In this situation they should be used every other, or preferably, every third night.

While they are sometimes used for long periods of time, the only approved indication for benzodiazepine hypnotics is for "short-term management of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings and/or early morning awakening." Effort should be made to discontinue these drugs as soon as possible.

Flurazepam. Flurazepam (e.g., Dalmane®) was the first benzodiazepine derivative marketed solely as a hypnotic. Compared with the barbiturate and nonbarbiturate

hypnotics, flurazepam has a wider margin of safety and fewer drug interaction. It produces little or no effect on REM (rapid eye movement) sleep with few early morning awakenings. Whether or not a true withdrawal phenomenon exists has yet to be clarified.

In some patients, flurazepam remains effective at constant dosing when administered for up to 28 consecutive nights. However, it suppresses delta (the most restful and refreshing) sleep, and its long-acting metabolite accumulates over time. Impaired daytime functioning, especially in elderly persons, can lead to falls resulting injuries. Peak plasma levels are noted within 30 to 60 minutes.

Temazepam. The major advantage of temazepam (e.g., Restoril®) is its short-to-intermediate elimination half-life of 9.5 to 12.4 hours. Temazepam produces a full night's sleep with little early morning awakenings. However, its half-life may increase to 20 to 30 hours in elderly individuals. Possible accumulation and morning hangover must be monitored with repeated use. The manufacturer of Restoril® has introduced a 7.5 mg dosage strength specifically for geriatric patients.

Temazepam shares similar properties with flurazepam with respect to effects on sleep. With doses of 15 to 30 mg, temazepam increases total sleep time and decreases the frequency and duration of nocturnal awakenings. It suppresses delta sleep during the first half of the night, although it decreases REM sleep during the second half. Because it may require 1 to 2 hours for onset of action, there is some question about its action to bring on sleep significantly faster in the patient who has difficulty falling asleep.

Triazolam An ultrashort to short-acting benzodiazepine hypnotic, triazolam (Halcion®) has an elimination half-life of 1.5 to 5.5 hours; peak plasma levels are reached within 30 to 60 minutes. Absorption appears to be as quick as that of flurazepam, but

elimination is more rapid. Triazolam suppresses REM sleep in the first half of the night, but appears to increase it during the second half.

Triazolam has little effect on delta sleep. This is its primary distinguishing difference from other benzodiazepines. Triazolam is also the least likely of all benzodiazepines to produce morning hangover. At a dose of 0.25 mg, it is practically nonexistent. As with flurazepam and temazepam, triazolam increases the total quality of sleep, decreases nocturnal awakenings, and increases total sleep time.

Controversy over Halcion® has been mounting since its introduction to the American market in 1982. While it is both safe and effective when used properly, triazolam has been associated with higher levels of bizarre and psychic side effects than with the other benzodiazepines. Halcion® became the number-one prescribed hypnotic soon after its release, but by 1988 its manufacturer discontinued the 0.5 mg dose and advised physicians that lower dosages should be prescribed.

By mid-October 1992, Argentina, England, Finland, Holland, Jamaica and Norway had removed triazolam from their markets, and France and New Zealand had removed the 0.25 mg strength.

In late 1991 after in-depth discussions with FDA, Halcion's manufacturer agreed to a number of labeling changes to enhance its safe use, to package the tablets in a 10-dose packet for retail use, and to include a patient information leaflet in the package (Table 4). It also announced it was planning to undertake a 10,000 patient clinical study to compare the safety of Halcion® with other hypnotics.

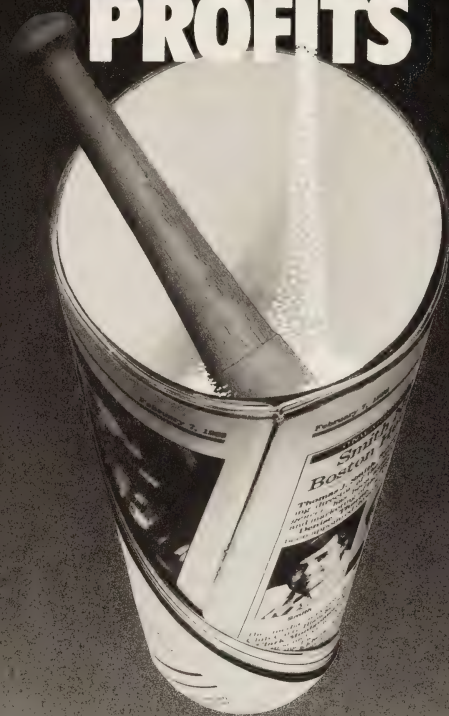
A major concern with triazolam is its tendency to cause psychomotor impairment, psychologic adverse effects, and a very specific type of memory impairment called anterograde amnesia. Anterograde amnesia is the loss of memory about information which is acquired after the hyp-

Patient Information for Halcion

To assure the safe and effective use of Halcion, you should heed the following precautions:

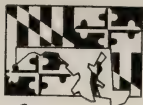
1. Halcion is a prescription medication and, therefore, should be used only as directed by your doctor. Follow your doctor's advice about how to take it, when to take it, and how long to take it. As with other prescription medication, Halcion should be taken only by the individual for whom it is prescribed.
2. Do not extend your use of Halcion beyond 7-10 days without first consulting your physician.
3. If you develop any unusual and disturbing thoughts or behavior during treatment with Halcion, discuss such problems with your doctor.
4. Inform your doctor about any alcohol consumption and medicine you are taking now, including drugs you may buy without a prescription. Do not use alcohol while taking Halcion.
5. Do not take Halcion in circumstances where a full night's sleep and elimination of the drug from the body are not possible before you would again need to be active and functional, because amnesiac episodes have been reported in such situations.
6. Do not increase the prescribed dose except on the advice of your doctor.
7. Until you experience how this medication affects you, do not drive a car or operate potentially dangerous machinery, etc.
8. Be aware that you may experience an increase in sleep difficulties (rebound insomnia) on the first night or two after discontinuing Halcion.
9. Inform your doctor if you are planning to become pregnant, if you are pregnant, or if you become pregnant while you are taking this medicine.

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notic is administered and before sleep onset.

Anterograde amnesia is not unique to triazolam. Other benzodiazepines and barbiturates also produce anterograde amnesia to lesser extents. It appears to be a function of dosing and the speed of onset of action. The higher the dose and the quicker a drug puts one to sleep correlates significantly with the anterograde amnesic properties of the drug. Any individual who falls asleep in less than 6 or 7 minutes has a high likelihood of experiencing anterograde amnesia. The safety of triazolam has also been of concern due to its association with traveler's amnesia. This is a form of anterograde amnesia that occurs when an individual uses a short-acting hypnotic to induce sleep while flying across time zones. Following ingestion of the drug and arrival at the airport (i.e., checking in or getting comfortable, etc.), the traveler has only limited, if any, recall of events that occur from check-in to arrival at his/her destination. Ingesting alcoholic beverages during the flight further complicates the situation.

The precise reason for anterograde amnesia is not yet known. Hastened sleep onset may interfere with the brain's ability to assimilate information for long-term memory. This would disrupt consolidation of memory, and hence, recall the next day.

Quazepam. Quazepam (Doral®) reportedly has strong specificity for the omega-1 receptor subtype. While the half-life of the parent compound is 39 hours, one of its metabolites, N-desalkyl-1-oxoquazepam, is identical to the long-acting active metabolite of flurazepam, N-desalkyl-flurazepam. Peak plasma concentrations are noted in 2 hours. Quazepam provides a full night's sleep with few early morning awakenings and little rebound insomnia. However, it is associated with next-day sedation.

Estazolam. Estazolam (ProSom®) has a relatively rapid onset of activity with few nocturnal or early morning awakenings, and increased total sleep time, depth of sleep and sleep quality. It provides a full night's sleep, little rebound insomnia, and has not demonstrated tolerance in clinical trials.

Peak plasma concentrations are achieved within 2 hours of the recommended dose, and its onset of action is similar to that of flurazepam and triazolam. Its half-life is 10 to 24 hours of the recommended dose. With chronic dosing, peak levels become 1.5 to 2 times as high as that following a single dose. Because the drug is rapidly absorbed, it can increase the onset of sleep significantly (a distinct advantage over temazepam) and provide a duration of action between flurazepam and triazolam.

Adverse Effects and Safety

Adverse effects of benzodiazepines are partially dose-dependent. For example, rebound insomnia with triazolam is reported to be more prominent with 0.5 mg than with 0.25 mg doses, and can be lessened by tapering the dose downward. Studies show that benzodiazepines impair performance in a dose-dependent fashion. Other trials confirm that benzodiazepines impair performance in a dose-dependent fashion. Other trials confirm that benzodiazepines with long biological half-lives are more likely to impair next-day performance. Thus, it is clear that the lowest possible dose should be used. Table 5 compares the adverse effect profiles of benzodiazepine hypnotics with short- and long-acting elimination half-lives.

Benzodiazepines are relatively safe. However, they should not be given to patients with suicidal tendencies. While barbiturates and other hypnotics have been used successfully to commit suicide, the potential for death in benzodiazepine derivative overdose is low unless they are taken concurrently with other CNS depressant drugs including benzodiazepine derivatives, and should be prescribed in limited quantity so that there is less potential for intentional or accidental overdose.

There are few potential interactions with other drugs and diseases and benzodiazepines. The most important drug-drug interaction occurs with other CNS depressants which cause additive effects when taken concurrently. While the significance is questionable, levels of flurazepam, quazepam, and their long-acting metabolite N-desalkylflurazepam can accumulate when taken with cimetidine (Tagamet®) and other drugs which interfere with oxidative metabolic processes. Liver disease and reduced liver function seen with advanced age can potentiate benzodiazepines.

Comparison of Adverse Effect Profiles of Benzodiazepine Derivatives with Short- and Long-Acting Half-lives

Characteristic	Short-acting	Long-acting
Accumulation with repeated use	No	Marked
Hangover effects the next day	Mild	Moderate
Tolerance	Moderate	Mild
Anterograde amnesia	Moderate	Mild
Risk of rebound amnesia	Moderate	No
Risk of early morning insomnia	Mild	No
Risk of daytime anxiety	Mild	No
Anxiolytic effects the next day	No	Moderate
Full benefits with the first dose	Moderate	Moderate

Table 3

Patient Advice for Benzodiazepines

- Take this medication with one-half to one full glass of water or other liquid at least 15 minutes before going to bed. The dose can be followed by a light snack.
- If you have been taking a benzodiazepine in large doses or for long periods of time, do not stop taking the medicine abruptly without consulting your doctor. It may be best to gradually reduce the dosage. Some people experience disturbed sleep for 1 or 2 days after discontinuing this medication. This should go away in a few days. If it continues, contact your doctor.
- This medicine may cause drowsiness in the morning. Make sure you are alert before driving or operating hazardous equipment.

□ Bizarre mental effects have occurred from simultaneous ingestion of alcohol and benzodiazepines. It is best to avoid alcohol while taking this medication.

The Next Generation

Zolpidem tartrate (Ambien®) is a new hypnotic drug that is chemically unrelated to either the barbiturates or the benzodiazepines. It has been marketed in Europe since 1987. It was approved for marketing in U.S. in late December, 1992, and introduced into therapy in the spring of 1993. Zolpidem is indicated for the short-term treatment of insomnia.

Using polysomnography (the process for recording sleep physiology by measuring movement of the eyes and

muscles electronically), clinical studies have investigated zolpidem's action as a hypnotic with emphasis on how the drug affects sleep architecture. It shortens the onset (sleep latency) of stage 1 which is the transition period between wakefulness and sleep. Zolpidem can also increase the duration of sleep.

Sleep efficiency is a means for gauging the efficacy of a hypnotic to maintain sleep. Sleep efficiency is expressed as the ration of the percentage of time a person is asleep divided by the total time in bed.

A study has demonstrated the statistically significant results of zolpidem (10 mg) on sleep efficiency when administered nightly over 35 days. This study also supports the safety and effectiveness of zolpidem for chronic treatment.

Another desired outcome for a hypnotic is to preserve sleep architecture or sleep quality. A hypnotic must be evaluated for its effects on the various element or components of sleep. Zolpidem preserves, and slightly increases, NREM (non-rapid eye movement) stages 3 and 4 sleep activity. Recall that NREM stages 2 and 4, collectively, are called delta (deep, restorative) sleep which is defined as the most restful sleep period.

Zolpidem has only minimal effect on modifying sleep architecture when used at doses up to 10 mg. At higher doses, it may prolong the REM latency, and decrease total REM in the first four hours of sleep. However, some reports show that zolpidem may actually increase total time spent in delta sleep in some insomniac patients.

The tendency to develop tolerance to zolpidem has been investigated extensively. Only a slight degree of tolerance is reported. In clinical investigations, there does not appear to be significant loss of efficacy with continued administration for up to three months. This observation, and the results of animal trials, infer that tolerance develops slowly, and to only a small degree.

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Zolpidem has been evaluated for abuse potential. In one clinical trial, 15 men who had a history of hypnotic drug abuse received increasing doses of zolpidem, triazolam or placebo given in a double-blind, cross-over design. Both drug treatments increased subjective responses which are reported to be desirable by abusers of sedative drugs. Zolpidem and triazolam showed little difference in this respect. Zolpidem was correlated with adverse effects including nausea and vomiting, light-headedness, dizziness, and queasiness. Particularly troublesome at higher dosages, this would tend to decrease the abuse liability of the drug. Like the benzodiazepines, zolpidem is classified as a Schedule IV controlled substance by the Drug Enforcement Agency.

Withdrawal symptoms following long-term administration have not been reported. Although it is typical for patients to have at least one night of sleep disturbance after discontinuing benzodiazepines, studies with zolpidem have shown no evidence of rebound insomnia on discontinuation of treatment.

Pharmacokinetics

Following oral administration, zolpidem is rapidly and completely absorbed from the GI tract. Bioavailability of approximately 70 percent is achieved after doses of 5 to 20 mg. The mean peak plasma drug concentration occurs approximately 2.2 hours after administration.

Zolpidem is bound to plasma protein by approximately 92 percent. The fraction of unbound drug in plasma can increase by 11 percent in patients with cirrhosis of the liver, and 15 percent in individuals with chronic renal insufficiency. The drug is metabolized completely. Three primary metabolites have been identified, all of which are devoid of significant pharmacologic activity.

Elimination half-life ranges from 1.5 to 2.4 hours in healthy persons. In persons with cirrhosis, the half-life

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is increased to 9.9 hours. In persons with renal disease, the half-life will be increased to 3 hours. It is, therefore, recommended that patients with hepatic or renal disease receive lower doses. The same is true for elderly patients. The usual adult dose is 10 mg while the dose for geriatric patients is 5 mg.

One investigation reported the results of two 3 month trials that compared zolpidem with triazolam. These were large, out-patient studies of 260 patients who received zolpidem 20 mg or triazolam 0.5 mg each night for 90 days. End points measured were sleep latency and duration, and overall sleep quality. Both hypnotics provided significant improvement over placebo in all measured responses. There were no statistically significant differences in any end points between zolpidem and triazolam.

Elderly persons may display slightly higher peak blood concentrations and $t_{1/2}$ values than younger persons. The same pharmacokinetic parameters are reported to be reduced in pediatric patients. As stated earlier, zolpidem is available in a 5 mg dosage strength for geriatric use.

Summary of Zolpidem Activity in Treatment of Mild Sleep Disturbances

- Rapid onset of action
- Increased total sleep time
- Tolerance not a significant issue
- Low incidence of next-day unwanted CNS side effects
- Natural sleep stages preserved

Table 6

The profile of the clinical effects and safety of hypnotics is important for geriatric patients because their sleep patterns are, on average, of shorter duration and more fragmented than those of younger persons.

They experience less delta (restful) sleep and are more sensitive to the effects of centrally acting drugs. Because their metabolic and excretion processes are reduced due to the aging process, elderly persons are more prone to side effects.

One interesting study looked specifically at these factors in 30 elderly non-insomniac volunteers. The study was a randomized, placebo-controlled, three-period crossover study to determine the effect of 5, 10, 15 and 20 mg doses of zolpidem versus placebo.

Polysomnographic studies showed a significant decrease in sleep latency and increase in sleep efficacy at all doses. When questioned about their subjective feelings, the subjects reported falling asleep faster and easier, with fewer awakenings and improved total sleep time and sleep quality. There were no consistent effects on next-day memory or performance.

Adverse Effects and Toxicity

Adverse effects reported for zolpidem are extensions of its sedative action and are dose related. Those noted include somnolence, light-headedness and dizziness. Gastrointestinal upset (nausea, vomiting, and pain) and headache are also reported.

While it is difficult to generalize on the potential for adverse effects in every patient, there has been a report on the results of five clinical trials which evaluated the potential of zolpidem to cause adverse psychomotor performance. At times up to 11 hours after zolpidem administration and at doses up to 20 mg, there were no residual effects on psychomotor function or daytime sleep latency.

Zolpidem does not appear to adversely affect the respiration rate during sleep in otherwise healthy patients, nor does it appear to modulate arterial blood gas measurements or control of breathing in persons with severe chronic obstructive pulmonary disease. However, since zolpidem complicates breathing

problems in patients with obstructive sleep apnea, it should not be given to persons with this disorder.

Safety in overdosage is not as clear as with benzodiazepines. However, no fatalities have been reported with dosages up to 400 mg. Flumazenil (Mazicon®), a benzodiazepine receptor antagonist, is an effective antidote for zolpidem.

Drug Interactions.

A number of studies have reported on zolpidem's potential to cause drug interactions. The drug's pharmacokinetics were not modified when given concurrently with chlorpromazine (e.g., Thorazine®) 50 mg, haloperidol (e.g., Haldol®) 2 mg, or imipramine (e.g., Tofranil®) 75 mg. Moreover, there were no alterations in pharmacokinetic values of the psychotic medications. Repeated administration of cimetidine (Tagamet®) 1 gram per day or ranitidine (Zantac®) 150 mg twice daily for 19 days did not affect the pharmacokinetics of zolpidem 20 mg, given on day 2 and day 17 of treatment with the H_2 blockers. As well, there was no change in the pharmacokinetics of the H_2 blockers. No effect on prothrombin time was seen after four days of zolpidem 20 mg given to individuals receiving warfarin.

Dosage and Administration

The efficacy of zolpidem to induce sleep has been evaluated in oral doses ranging from 5 to 40 mg. The usual reported dose for most trials is between 10 and 20 mg. Most published data so far have indicated there are no differences in hypnotic effectiveness between 10 and 20 mg doses, although higher doses are associated with increased adverse effects. The recommended dose is, therefore, 10 mg administered immediately before retiring after the decision to go to sleep has been made because of the short sleep latency period. Since there is a possibility of altered phar-

macokinetics and increased risk for adverse effects, the dosage in elderly and debilitated persons should be 5 mg. If ineffective, it may be increased to 10 mg in these patients.

Summary

The imidazopyridine derivative hypnotics are a new group drugs. Rarely have drugs been so close to matching the "ideal" therapeutic agent. Table 6 summarizes the activity of zolpidem in treatment of mild sleep disturbance. Table 7 summarizes its use in elderly patients.

Summary of Action of Zolpidem in Elderly Patients

- Stages 3 and 4 and REM preserved
- Not associated with next-day memory loss
- Low abuse and dependence potential
- Minimal to no rebound insomnia at recommended doses
- No active metabolites formed
- Little or no daytime sedation reported

Table 7

Studies of zolpidem have shown the imidazopyridine derivatives are well suited for patients with short-term or mild sleep disorders. It has a rapid onset of action. It also reduces night-time awakenings, increases total sleep time, and preserves natural sleep stages. It has not been associated with tolerance, and has not shown unwanted next-day CNS side effects. The imidazopyridines appear to be particularly promising for use in elderly patients.

For example, zolpidem does not require hepatic metabolism and it has a low level of side effects. It helps preserve delta and REM sleep, and has shown minimal rebound insomnia at recommended dosages. It has demonstrated little or no next-day

sedation thereby lessening the chance of falls and accidents that the elderly are predisposed to with other hypnotics. Zolpidem has not been associated with memory loss, another potential problem for geriatric patients.

Patient Advice for Zolpidem

- The intended use for this medication is to treat insomnia.
- You should take this medication with a glass of water after you have decided to go to sleep. Be sure to allow enough time to completely swallow the tablet before lying down.
- Most people do not experience next-day drowsiness or "hangover" from this medicine. However, if you do notice you are drowsy in the morning, do not drive a car or perform hazardous tasks until the drowsiness passes.
- It is important that you take this medicine exactly as your doctor has instructed. Do not take more doses or take longer than instructed without consulting your doctor.
- Some people experience disturbed sleep for 1 or 2 nights after discontinuing sleeping medications. This should go away in a few days. If it continues, contact your doctor.
- Do not take a nonprescription sleep aid without first asking your doctor.
- Tell your doctor if you are pregnant, plan to become pregnant or are breast-feeding an infant.
- Side effects from this medication are relatively rare. However, tell your doctor if the following occur: unusual thoughts, dreams or nightmares, persistent fever or sore throat, mouth sores, difficulty breathing, irregular heartbeat, yellow coloration of the skin or eyes, excessive confusion or excitement.
- Do not keep or use outdated medication.
- Keep all medications out of the reach of children.
- Federal law prohibits giving this medication to any person other than yourself.

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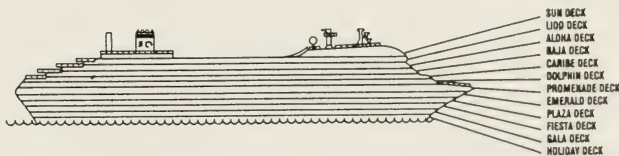
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Continuing Education

Continuing Education Quiz

January 1994 -- Hypnotics

This month's questions are taken from the article on President Clinton's health reform proposal in this issue. Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$30 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by June 30, 1994. A continuing education certificate for three contact hours (three credits) will be mailed to you within six to eight weeks. Please type or print clearly.

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1. Persons taking which type of barbiturate are at greater risk for redeveloping dependency?
 - a. long-acting
 - b. short-acting
2. All of the following statements about barbiturates are true except:
 - a. they have narrow margins of safety
 - b. they suppress delta and REM sleep
 - c. they inhibit hepatic microsomal enzymes
 - d. tolerance occurs, leading to decreased efficacy inducing and maintaining sleep
3. Barbiturates are more likely to cause death in overdose than are the benzodiazepines because barbiturates cause a higher degree of:
 - a. cardiac damage
 - b. kidney malfunction
 - c. liver toxicity
 - d. respiratory depression
4. To be maximally effective, hypnotic drugs should be:
 - a. rapidly absorbed
 - b. slowly absorbed
5. The newer class of drugs that seems to be nearly ideal hypnotic is the:
 - a. thiothymidines
 - b. benzodiazepines
 - c. phenazopyridines
 - d. imidazopyridines
6. The drugs referred to in question #5 have all of the following properties except:
 - a. low abuse potential
 - b. rapid onset of action
 - c. long duration of action
7. Rebound insomnia is associated with abrupt discontinuance of:
 - a. long-acting barbiturates
 - b. short-acting barbiturates
8. In the study referred to in this lesson, the largest percentage of patients taking hypnotic medications used them:
 - a. 1-2 days
 - b. 3-13 days
 - c. 2-3 weeks
 - d. 1-3 months
9. The ideal elimination half-life for a hypnotic for a patient who was difficulty falling asleep is:
 - a. 1-2 hours
 - b. 3-4 hours
 - c. 5-7 hours
 - d. 8-12 hours
10. Which of the following hypnotic has been placed in schedule II by DEA?
 - a. chloral hydrate
 - b. diazepam
 - c. glutethimide
 - d. methaqualone
11. Anterograde amnesia refers to loss of memory:
 - a. about dreams occurring while taking a hypnotic
 - b. that comes and goes over several weeks
 - c. about information between taking a hypnotic and falling asleep
 - d. on how to answer questions in CE articles

Additional questions on the back of this page....

12. In addition to their hypnotic action, benzodiazepines exert all of the following activities except:
 - a. anticonvulsant
 - b. anti-inflammatory
 - c. anxiolytic
 - d. muscle relaxant
13. The sites of action within the CNS that benzodiazepines bind with are called:
 - a. adrenergic receptors
 - b. cholinergic receptors
 - c. endorphin receptors
 - d. omega receptors
14. Which subtype receptor in question #3 appears to be most important for including and maintaining sleep?
 - a. subtype-1
 - b. subtype-2
 - c. subtype-3
15. The following interact significantly with benzodiazepines.
 - a. antihypertensives
 - b. CNS depressants
 - c. NSAIDs
 - d. anticonvulsants
16. What is the inhibitory neurotransmitter in the brain stem and foreparts of the higher centers in the brain?
 - a. acetylcholine
 - b. dopamine
 - c. gamma aminobutyric acid
 - d. serotonin
17. The physiological process that results from action of the neurotransmitter referred to in question #16 is that it enhances entry of which of the following ions into neurons?
 - a. chloride
 - b. sodium
 - c. bicarbonate
 - d. calcium
18. The primary distinguishing difference for triazolam compared to other benzodiazepines is that it:
 - a. causes more morning hangover
 - b. has a longer elimination half-life
 - c. takes longer to induce sleep
 - d. has little effect on delta sleep
19. Which of the following is classified as an intermediate zone benzodiazepine?
 - a. chlordiazepoxide
 - b. quazepam
 - c. clonazepam
 - d. lorazepam
20. Temazepam exerts all of the following activities except:
 - a. increased total sleep time.
 - b. decreased frequency of nocturnal awakenings.
 - c. decreased half-life in elderly patients.
 - d. decreased duration of nocturnal awakenings.
21. Zolpidem is a member of which of the following chemical groups?
 - a. barbiturate
 - b. imidazopyridine
 - c. catecholamine
 - d. phenothiazine
22. Zolpidem appears to exert its action on which of the following neuronal receptor sites to the greatest extent?
 - a. Omega-1
 - b. Omega-2
 - c. Omega-3
 - b. Omega-4
23. Which of the following pharmacologic actions is common to both the benzodiazepines and zolpidem?
 - a. antianxiety
 - b. hypnotic
 - c. anticonvulsant
 - d. muscle relaxation
24. Based on the results of polysomnographic studies, zolpidem has been shown to induce all of the following except:
 - a. decreased stage 3 and 4 portions of NREM sleep
 - b. increased duration of sleep
 - c. minimal modification of sleep architecture
 - d. shortened sleep onset
25. The antidote for an overdose of zolpidem is :
 - a. deferoxamine
 - b. atropine
 - c. physostigmine
 - d. flumazenil

The Role of Pharmacy Technicians

Jee Hyun Kim, Pharmacy Student, UMAB School of Pharmacy

This article is the first in a series written by pharmacy students in the first course of the new entry-level Pharm.D. program at the University of Maryland School of Pharmacy. PHAR 516 (Pharmacy Practice and Education) is an introductory course which exposes the students to pharmacy practice, pharmaceutical sciences, ethics, communication, and critical thinking. One of the class assignments was to write a critical evaluation on one of three topics: pharmaceutical care, pharmacy technicians, or mail-order pharmacy. This course was developed by MPhA Past President Hene Zuckerman with the assistance of MPhA member and graduate student Diane McNalley.

Since the mid-1940s, pharmacists have been assisted by supportive personnel.¹ With increasing demand for pharmaceutical care, the role of the pharmacist's support system, more pointedly, the role of the pharmacy technician, should be expanded.¹ The importance of pharmaceutical care can be seen in a survey of patients, physicians, and third party administrators found in *American Pharmacy* (March 1990) that showed that personal drug counseling of prescriptions and over-the-counter products ranked at the top of the services provided by a pharmacist as being deemed most valuable.² However, because of this, the pharmacy technician becomes the focus of a heated debate: What are the advantages and disadvantages of the enhanced use and role of pharmacy technicians in pharmacy practice?³

An advantage to enlarging a technician's role is that it would free up the pharmacist to delve further in to patient counseling, drug therapy input, and case monitoring, thereby expanding the role of the pharmacist as well. Such rote tasks as making labels, counting and pouring medicines, maintaining patient records, and preparing the final dispensing container are presently being performed by technicians. In a pilot project done by the Minnesota Society of Hospital Pharmacists, it was shown that pharmacy technicians could perform unit dose cassette checking with an accuracy of at least 99.94%.⁴

An added benefit to the use of technicians is one of economic value. The fact that pharmacy technicians are paid less than pharmacists leads to a two-fold advantage. The first is that it costs less to hire technicians to

do dispensary tasks rather than another pharmacist.⁵ The surplus funds can be used to improve the overall pharmacy by enabling the pharmacist to operate for more hours, getting better data management equipment, having more reference materials available to the patient, or enhancing the general appearance of the pharmacy. The second advantage comes from using the surplus funds to hire more technicians. By having more technicians, the pharmacist is able to concern him/herself more with pharmaceutical care.

The disadvantages associated with expanded pharmacy technician duties are equally as prominent as the advantages. As seen in the above literature, the lesser pay received by technicians acts as an incentive to hire them. This causes worry for some dispensing pharmacists who see their livelihood being threatened by technicians⁶: Who wants to pay more for something they can get cheaper? Thus, either less pharmacists will be employed or they will receive a cut in their salary; both options being disagreeable. A decrease in the amount of pharmaceutical care being given, which would be counterproductive to the objective that is trying to be reached -- increased and more comprehensive pharmaceutical care.

Besides competing with pharmacists for positions, technicians would also be competing with pharmacy students and externs who need the work experience.⁶ Again, this will produce a smaller population of future practicing pharmacists.

The image of pharmacists in society might also suffer if people think that pharmacy technicians can so easily take over many functions of

Plans for National Technician Certification

At the 1993 Mid-Year Clinical Meeting of the American Society of Hospital Pharmacists, ASHP, the American Pharmaceutical Association, the Michigan Pharmacists Association and the Illinois Council of Hospital Pharmacists announced the establishment of a national voluntary certification program for technicians. Citing competing state programs, the associations explained that a cooperative effort in developing a voluntary certification program will ultimately provide employers with "technicians who have already proven that they have mastered a basic core of knowledge."

Responding to the announcement, the National Association of Retail Druggists and the National Association of Chain Drug Stores issued a statement opposing the program. NACDS President Ron Ziegler added that "it is not the role of APHA, ASHP or any other entity to develop a national voluntary certification program for all of pharmacy."

the traditional pharmacist. Ideas that pharmacy may not really be a necessary health profession could be considered, especially in lieu of the fact that technicians do not receive the same amount of education and training as do pharmacists. Which could lead one to ask what is the point of funding pharmacy education.

However, this issue of education and training is the biggest disadvantage of expanding technicians' roles. The technician has not been formally educated in terms of drug chemistry and interactions, or human biology, or

pharmacokinetics, or a whole array of other subjects. Technicians know only the actions of being a pharmacist, but not the knowledge of a pharmacist. Because of this lack of theoretical understanding, there is a greater chance for mistakes to be made by a technician. And if these mistakes should occur, it is the pharmacist who must bear the responsibility.

Another disadvantage is that there is presently much confusion and contention as to what a pharmacy technician is and does.⁷ Expanding technician roles would only add to this chaos. Some states do not even recognize the existence of pharmacy technicians.⁵ There are currently many moves being made toward recognizing and certifying technicians and requiring some type of core education and training, such as in Arkansas, Washington, and Illinois. However, there is presently no standardization among state certification and education/training methods.⁶

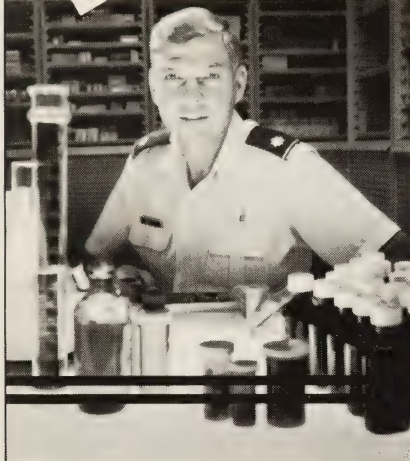
By assessing both the advantages and disadvantages of expanding technician functions, I feel that at the present time it is not wise to increase technician roles (assuming that they are recognized) even though there is a great need for pharmacists to devote more of their time and attention to pharmaceutical care. I believe this on the basis that the goal of a pharmacist is to do everything possible to maintain the highest level of care for patients.⁸ Even if drug dispensing may seem to be an infinitesimal aspect of pharmacist functions, it is nonetheless enormous in importance because it is this realm of medicine which the pharmacist presides over. Without it, there would be no need for pharmaceutical care. This is not to say that technicians are incompetent. Hardly. As seen in the Minnesota pilot program, technicians are capable of a high degree of self-supervision, but what about those who are not? Should we as pharmacists gamble with our patient's welfare in such a way? No. It is the responsibility of the pharmacist to maintain

the integrity of his profession, be it in the form of dispensing or counseling. **R**

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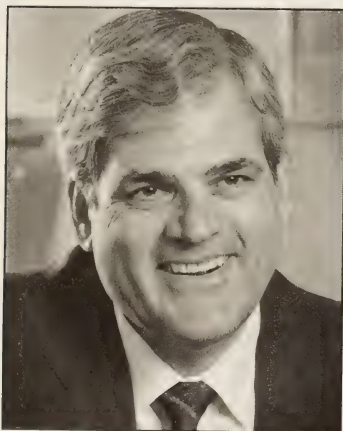
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The Board Responds

Recent Opinions That Affect Maryland Pharmacists

Steven Cohen, P.D., President, Maryland State Board of Pharmacy



Occasionally, the Maryland State Board of Pharmacy is asked to issue advice to aid pharmacists in their daily practice. The Maryland Pharmacists Association has asked the Board to give guidance on two issues, both related to access and distribution of patient and/or prescription information.

MPhA Question The Anne Arundel County Police sent letters to pharmacies informing them that they would "periodically conduct an investigative audit of [their] prescription files." What legal right does law enforcement have to inspect pharmacy records without subpoenas or search warrants?

The Board of Pharmacy advises that the Anne Arundel County Police have no authority to require a pharmacy to produce records in the absence of a subpoena or search warrant. Although the Board and the Division of Drug Control have the authority to inspect pharmacy records under the Pharmacy Practice Act, there is no parallel authority granted to the police.

MPhA Question Many times pharmacists become aware that an individual is "shopping" local pharmacies in order to obtain multiple unauthorized prescriptions for controlled substances or other medications. Are there any state or federal statutes or regulations that would prevent the sharing of patient or prescription information between pharmacies in relation to a suspected "shopper?"

If a pharmacist suspects illicit activity, the first logical step to take is to contact the prescriber's office for confirmation of the prescription. If the prescriber's office is closed, and the pharmacist remains uneasy about whether the prescription is genuine, he or she may decline to fill the prescription. If a prescription appears to be *forged*, the pharmacist may hold the prescription and contact the police while the suspect is waiting for the prescription to be filled. In a situation where a pharmacist did not fill a prescription because it became evident that the prescription was bogus, there do not appear to be any state or federal prohibitions against sharing that information with another pharmacist.

In any situation where a pharmacist suspects substance abuse, there is a corresponding responsibility on the pharmacist's part to determine whether a prescription is medically justified. Where concerns arise with respect to such topics as the frequency, amount, or choice of a scheduled drug, the pharmacist should question the prescriber about the patient's need for the medication. If the prescriber's answers are unsatisfactory, the pharmacist may refuse to fill the prescription or may contact the Division of Drug Control or both. If a pharmacist reports a problem, the Division of Drug Control may audit the prescriptions of the authorized prescriber to determine whether there is a pattern of abuse.

R

Court Endorses OBRA 90 Requirements

David B. Brushwood, J.D.



It is clear to most people observing the pharmacy scene today that the OBRA 90 mandate, as interpreted by state regulatory agencies, will expand for pharmacists the legal expectations imposed by courts of law. In a recent opinion of the California Supreme Court, that view was validated in no uncertain terms.

The case in which the patient counseling and drug use review aspects of OBRA 90 were discussed by the California Supreme Court really dealt with a seemingly unrelated matter. The parents of a child who had been mistakenly dispensed a medication with erroneous directions to take too high a dose, sued the pharmacy arguing that the parents should be able to recover from the pharmacy for their own injuries (emotional distress) as direct victims of the pharmacy's negligence. The question was not whether the child could sue. Clearly the patient who is harmed by a pharmacist can sue the pharmacy. The question was whether the *parents* of the patient could sue the pharmacy based on their own harm.

The court ruled that the parents could not sue the pharmacy, because to impose upon a pharmacy a duty to avoid emotional distress to parents of patients would inevitably enlarge the potential liabilities of practically all providers of medical goods and services obtained by parents solely for the treatment of their children, or by other care-givers solely for the treatment of dependent family members. Because the plaintiffs in the case were not the patients for whom the pharmacy dispensed the prescribed medication, they were not permitted to recover as direct victims of the

defendant's negligence.

However, the court noted that "The pharmacist must not only select, measure, and label the prescribed medication in accordance with the doctor's orders, but must also be alert to errors or problems and bring them to the doctor's attention. Pharmacists also spend substantial amounts of time advising patients about the proper use of a prescribed drug and its possible side effects or interaction with other medications."

The court made it clear that a pharmacist has a responsibility to screen prescriptions and provide appropriate counseling

The court also noted the requirement in California law that the pharmacist must provide oral consultation about a prescription drug to the patient or the patient's agent. The court stated in the majority opinion, "The obvious purpose of providing for consultation with a patient's agent has nothing to do with the agent's personal welfare; the purpose is simply to assure that the pharmacist's advice is put to good use for the benefit of the patient even in situations in which the patient would be unable to understand the advice."

Of the seven justices on the court, five sided with the majority opinion, resulting in dismissal of the case against the pharmacy. Yet, although the pharmacy won the case, because the plaintiff was not the patient, the court made it clear that a pharmacist

has a responsibility to screen prescriptions and provide appropriate counseling. When a patient is harmed by the failure of a pharmacist to do these things, an action for negligence against the pharmacist by the patient will be allowed.

The two dissenting justices, who would have permitted liability of the pharmacy to the parents, added language in their minority opinion that pointed to expanded responsibility of pharmacists. Justice Kennard stated a contrary view to that of the majority in this way: "Inevitably, when the patient is an infant, the pharmacist's duty to provide appropriate directions for use of the prescribed medication will be met through communication with someone other than the infant patient. In most such cases, including this one, that agent of the patient is one of the infant's parents. Thus it is clear that when the patient is an infant, the pharmacist must, in the performance of his or her professional duty, provide the parent with directions to be followed in administering the medication to the infant."

The primary lesson to learn from this case is that the requirements of OBRA 90, as implemented by the states, are far more than a request for action by a regulatory agency. They are more than a lofty goal to aspire to at some time in the future, when current barriers to expanded practice have been overcome. The screening of prescriptions, patient counseling, and patient profile requirements mandated by OBRA 90 elevate the pharmacist's standard of care today, not tomorrow. Because litigation takes time, and because appellate opinions are the only legal opinions that consistently are reported and publicized, it will be several years before reports begin to surface of cases in which pharmacists have been held liable under OBRA '90 mandated state laws for harm caused to a patient based on an incident that occurred after January 1, 1993 (the effective date of the OBRA 90 mandate). Thus it might appear that some judges deciding cases in 1993 and 1994 are not recognizing the OBRA 90 mandate, because those cases are based on incidents that occurred prior to January 1, 1993. Pharmacists should not be fooled by this appearance of reluctance. Incidents that occur after January 1, 1993 will be resolved by courts based on the OBRA 90 standards. The Supreme Court of California has made that clear. **R**

Based on *Huggins v. Long Drugs*, 1993 Cal. Lexis (November 17, 1993).

About the Author

David Brushwood is Professor of Pharmacy Health Care Administration at the University of Florida. His articles on cases affecting pharmacists and pharmacy are provided as a courtesy to state pharmacist associations. Questions on legal issues affecting Maryland practice should be directed to your legal representative or the Maryland State Board of Pharmacy.



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The Maryland Pharmacist

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NO. 2



Test Your Knowledge

Board of Pharmacy
Exam Inside

What's Your Pharmacoeconomics I.Q.?

Test yourself! Answers at bottom of page.

1. Outpatient prescription medicines account for approximately what percent of total health care spending?
a. 5% b. 10% c. 15% d. 20%
2. How many years of patent life typically remain once a new drug is approved for marketing?
a. 17 b. 10-12 c. 3-5 d. 5-7
3. Which amount is the closest to the actual cost of dispensing a prescription in a full-service pharmacy?
a. \$2.00 b. \$3.35 c. \$6.00 d. \$1.25
4. Out of every ten new drugs marketed, on average, how many achieve sufficient revenue to cover costs and make a profit?
a. 8 b. 2 c. 6 d. 1
5. Considering drug prices and manufacturing wages in the U.S. & Mexico, how long do Mexicans work compared to Americans to pay for Rx drugs?
a. same # hours b. Half as long c. more than twice as long
6. What is the current estimated cost of bringing a new drug to market?
a. \$175 million b. \$359 million c. \$500 million d. \$100 million
7. Which component of health care costs are patients most aware of because they pay out of pocket?
a. physician b. prescription c. hospital d. emergency room
8. What percent of sales, on average, is spent on research by research-intensive pharmaceutical manufacturers?
a. 25 b. 16 c. 8 d. 11
9. Total health care expenditures have risen to almost 13% of GNP since 1960. How have pharmaceutical costs behaved as a % of GNP during that period?
a. risen to 3% b. fallen to 0.5% c. held nearly constant under 1%
10. If pharmaceutical industry profits were eliminated, how much would this reduce total national health care costs?
a. 3% b. 5% c. less than 1% d. 10%

Answers: 1 a. 5%; 2 d. 5-7; 3 c. \$6.00; 4 b. 2; 5 c. more than twice as long; 6 b. \$359 million; 7 b. prescription; 8 b. 16; 9 c. held nearly constant under 1%; 10 c. less than 1%

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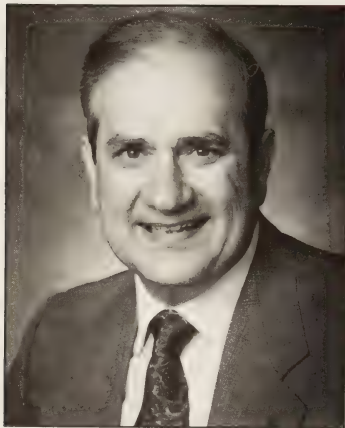
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President's Commentary

Howard Schiff, P.D.



Many members of volunteer organizations think that the organization is run by small cliques of people who need to feed their own already over-blown egos. You know the type.... people who like to see their names in print.... people who think that being in a leadership position gives them some extra measure of importance.... people who take turns giving each other awards at the end of the year.

I don't think this is true of the pharmacists involved with MPhA.

Just ask a member of the Legislative or Third-Party Committees. They're the ones who spend long hours of their own time in meetings in Annapolis or with state Medicaid officials. Their work is usually frustrating and results are almost never immediate -- if results ever occur at all. Sometimes some favorable action by a bureaucrat or legislative body is due to the groundwork laid from two, three or even five years worth of Committee members' efforts. For example, the salvage of the Pharmacy Assistance Program several years ago was due to the cooperative spirit that the Third-Party Committee had developed with the Department of Health and Mental Hygiene. For example, most of the pharmacy services portion of Maryland's Standard Benefit was due to long years of work and building MPhA's representation before the legislature and its committees.

These pharmacists participate in MPhA because of vested interests; that is, it is their own drive and desire to see the professional and proprietary interests of the pharmacy profession advance.

In 1991, MPhA's House of Delegates expanded and restructured the Board of Trustees to ensure that the Board better reflected the profession and our membership. According to the bylaws, it is the job of the Nominating Committee to present a slate of nominees that represents both geographical and practice specialty diversity. Our current Board has representatives from community/independent, community/chain, managed care, long term care, institutional care and hospital practice. One of our Trustees travels two to three hours every month to meetings, even in the winter.

Why am I telling you this? Because this month kicks off our annual elections. Ballots and candidate statements will be mailed to all active members of MPhA. I think that the list of candidates is one of the finest we've ever had.

These pharmacists aren't out to have their egos stroked. They're out to improve MPhA and pharmacy. When you receive your ballot, take time to read their individual statements and their biographical information. I think you'll find that all of them would be worthy of representing your interests. **R**

Board of Pharmacy Examination

An Opportunity to Test What You Really Know About Pharmacy

Richard D. Baylis, P.D., Director, Mid-Atlantic DUR, Inc.



1905 was an exciting year in the world of science, discovery, invention and politics. Theodore Roosevelt was president and busting the Trusts. There was a general strike in Russia and the first peoples Soviet was formed in St. Petersburg, a harbinger of events to come. Einstein published his Theory of Relativity. The Dominican Republic was invaded by US Marines to insure collection of US and foreign debts. The Marines stayed until 1907. Orville Wright flew his aircraft for 33 minutes, the longest duration of flight to date. The previous year, Madame Curie showed pitchblende contained two radioactive elements, Radium and Polonium. New York (National League) beat Philadelphia (American League) by 4 to 1 in the World Series. MPhA's President was M.A. Toulson, Louis Schulze was secretary and H.R. Rudy was treasurer. The Mayor of Baltimore was E. Clay Timanus and Edwin Warfield was Maryland's Governor.

In December of that year, Pharmacist J.H. Marsh moved from Michigan to Clatonia, Nebraska. Dr. Mash was certified as a physician from the College of Physicians and Surgeons of Lower Canada in 1860. In 1891, Dr. Mash took the Michigan examination for pharmacy and his rating of 78% was the highest of the class. When he took the following pharmacy examination in Lincoln, Nebraska he again scored the highest rating once again.

Dr. Marsh is quoted in the December, 1905 *Omaha Druggist* as saying "With regard to my rating at Lincoln, I must say it was a surprise to me, I expected to pass, but with nearer 70% that 82%, which I thought would be fairly well for a man well on the shady side of 60, as I supposed 37 would have wrought many changes. As is, the principal occupation of a druggist as I see it today is to dispense the preparations of about half a dozen enormous laboratories (and sell patent medicines). These firms supply almost every possible combination of medicine in the shape of tablets, elixirs, and sugar coated pills; nicer preparations, no doubt, than could ordinarily be turned out on a small scale at the private store. Forty years ago we had no tablets, no sugar coated pills, no elixirs, only five or six fluid extracts; we used to make everything at home, from start to finish. It was this, no doubt, that gave me such familiarity with crude drugs and processes, as to make it sort of second nature which could never be forgotten. The wheels of progress, however, do not roll backwards. The Trusts are here to stay, but it deprives the young clerk of much of the practice which is necessary to perfection. The patent medicine business has become too cumbersome for endurance, is a great damage to the trade and calls for radical action."

The Nebraska Pharmacists Association published this examination for their members in their journal last year. Unfortunately, no one had the answers. MPhA was asked to help locate the answers because our association is fortunate to have one of the most comprehensive historical pharmacy libraries in the country. In researching the answers, we have used the *United States Pharmacopeia* 8th Edition, 1905; *Remington's Practice of*

Pharmacy, 4th edition, 1905; *United States Dispensatory*, 1918, and *Dictionary of Medicine*, 9th Edition, 1885.

The questions must be answered with the knowledge of the day. Theory and practice have changed so rapidly in pharmacy, you cannot answer the questions from what you no about modern pharmacy and practice. For instance, emulsions were just beginning to be understood as a separate entity from mixtures. The pharmacist of that time did not comprehend the difference between oil-water and water-oil emulsions.

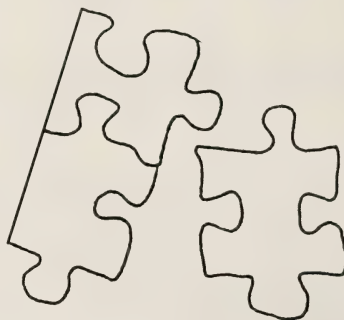
Of course, it wouldn't be fair to ask you to take the exam and then not provide you with the answers. The exam itself appears on pages 8 and 9. The answers begin on page 19.

We hope that you enjoy mulling over these questions as much as we did!

R

The comments of Dr. Marsh and the exam are reproduced by permission of the Nebraska Pharmacists Association.

Next month....



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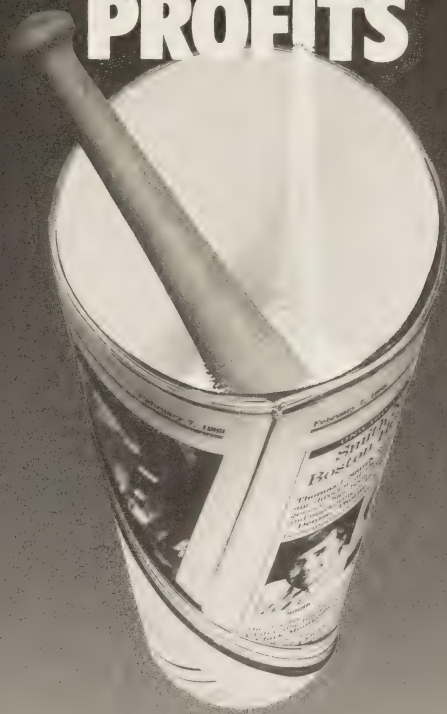
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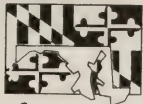
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Pharmacy Examination

November 8, 1905

A. Pharmacy Section

- What is the U.S.P.?
 - What is the meaning of the title liquor in the American pharmacopeia?
 - How is mucilage of acacia prepared?
 - How is mucilage of tragacanth prepared?
- What is a glycerite preparation? Name three.
 - Define glycerite of starch; for what is it mostly used?
 - What is an emulsion?
 - How may emulsions be classified?

B. Toxicology

- What are the doses of Mercurous Iodide; Mercuric Iodide; Mercurous Chloride; Mercuric Chloride; and Chloride of Gold?
- State the official name for Black Drops, its ingredients and the process for making. How much morphine per ounce?
- State the antidote for: Face Bleach, Creosote, Rough on Rats, Hair Dyes, Indelible Inks, and Embalming Fluid.
- Define: opisthotonos, asphyxia, clonic spasms, syncope, and catalepsy.
- Let "X" represent the dose of a certain drug; What would be the dose for a child of 1 year, 3 years, 7 years, 11 years, and 13 years?
- What are the symptoms of Aconite poisoning, and treatment thereof?
- Write the official name in full, and give the dose of: Fluid Extract Indian Hemp, Croton Oil, Extract Calabar Bean, Dog Button, and Henbane.
- Give the official name of the principal alkaloid obtained from Nux Vomica. Give a physical description, maximum dose and treatment in overdose.
- Give the official names and doses of five poisons, other than referred to in this list of questions.

C. Pharmacy Practice

- What is the pharmacopeial strength of a medicated vinegar?
 - How many vinegars does the pharmacopoeia contain? Name three and how are they made?
 - What is meant by hydroalcoholic tincture?
 - What is an etherial tincture?
- What is the menstruum used in the making of ammoniated tincture?
 - What is the percentage of alcohol contained in a medicated wine?
 - What is tannin and what are its most characteristic properties?
 - Name three different solvents for tannin.
- Antimonial powder. Give the synonym and the Latin official name. How is it prepared?
 - What are the ingredients of Aromatic powder?
 - Give the Latin official name of Compound Chalk powdered and give ingredients in preparing the same.
 - Compound Effervescing powder. Give the Latin official name, synonym and what ingredients are used in preparing it?
- What is sublimed sulphur, and what are its physical properties?
 - How is it used medicinally, and what is the dose?
 - How is washed sulphur prepared, and what is the purpose of adding ammonia in washing it?
 - Why is washed sulphur prepared for medicinal purposes?
- How many pill masses are official? Name them.
 - What are confections, and how many are official?
 - Give the general formula for triturations.
 - What trituration is official?
- What are cerates, and why are they so called?
 - How many cerates are official?
 - Cerate, give the Latin official name.
 - How is Camphor Cerate prepared?
- Benzoinated lard, what is the Latin official name?
 - How is Benzoinated Lard prepared?
 - What is Pepsin and where obtained?
 - How much coagulated egg albumen should it be capable of digesting?

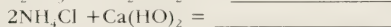
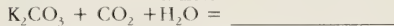
8. Criticize the following prescription.

Iodide Pot	Drs. 2ss
Hydrarg Bichloridi	Grs. 2
Alcohol	Oz. ss
Elix Calisaya	Oz. 3ss

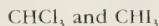
D. Chemistry

- What is specific gravity?
 - Give an example of a solid, a liquid, and a gaseous acid.
 - What is the strength and specific gravity of Sulphuric Acid?
- What colors are imparted to a non-luminous flame by compounds of:
 - Potassium
 - Sodium
 - Lithium
 - What is meant by a radical?
 - What is Qualitative and Quantitative analysis?
- Give the meaning of the following prefixes as used in chemistry: Bi., Sub., Per., and Hypo.?
 - Of what compounds is Hydrogen a constant constituent?
- Mention the Official compound of Boron.
 - Mention all of the official compounds of Lithium, and from which of these may all the rest be prepared?
- How may Sodium Acetate, Benzoate and Salicylate be prepared extemporaneously in solution?
 - What chemical change takes place when mixing a Seidlitz powder?
- From what is Ammonia gas obtained, and how are the Hydrate, Chloride, Carbonate and Acetate respectively produced?
- What is the principal compound of Silver?
 - Give the titles for its three forms.
 - In what substances is Red Precipitate resolved upon heating?
 - How is Nitro-glycerine made?
- Potassium -- Give symbol, source, description and official compounds.
- Give the on name for the following new USP Chemicals: Sulphonethylmethane, Sulphonethylmethanum, Phenylis Salicylas, Methylthionae Hydrochloridum, Hexamethylenamina.

10. Complete the following equations:



Give the common names for:



E. Materia Medica

Give the synonym, principal constituents, medical properties, official preparations and their doses, of the following:

- Asclepias
- Belladonnae Radix
- Gelsemium
- Podophyllum
- Colchici Radix
- Scilla
- Prunus Virginiana
- Eucalyptus
- Senna



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Advising Patients on "Switch" Drug Products

Part I: The Process, Pros, and Cons

Thomas A. Gossel, R.Ph., Ph.D., Interim Dean, Ohio Northern University

J. Richard Wuest, R.Ph., Pharm.D., Professor of Pharmacy, University of Cincinnati



The switching of prescription drugs to OTC status has been a somewhat controversial, yet dynamic component of modern therapeutics. Considering both OTC drug product ingredients and dosage strengths, more than 400 OTC products in use today were restricted to prescription only status in 1978.

Federal laws enacted throughout the first half of the 20th century to regulate drugs were designed to assure the safety and purity of drug products sold in the U.S. They did not differentiate prescription versus nonprescription drug status. Most emphasis was on the former. As a result, some manufacturers of OTC drug products were not always viewed as providers of ethical products.

Professional Attitude

There is a difference of opinion among pharmacists about the pros and cons of the prescription to OTC switch. The professional point of view is that it provides greater opportunities for patient counseling.

The economic view is that every prescription drug that becomes OTC ends the exclusive dispensing franchise pharmacists have. This opens the sale of the OTC version to non-pharmacy outlets which have already taken over 60 percent of OTC sales away from pharmacies.

Fueling the Switch

Several societal and economic factors have helped bring about the switch process (Table 1). Among

them is the national trend toward self-care. Consumer advocates argue strongly that self-medication is a basic human right and people should have greater choice in managing their own health. They feel that Americans are sophisticated, self-reliant and health conscious, and capable of making good decisions, balancing the benefits and risks of drugs.

Opponents are concerned with the process and the self-care movement. They cite deceptive advertising, misuse of medication, delays in medical treatment of serious disease or poisoning, and lack of professional supervision as reasons to maintain drugs on prescription status.

Others view the switch as a valuable alternative to escalating health-care costs. The premise is that safe and effective OTC products promote self-therapy which is easy to access without the expense of physician or pharmacist intervention. Proponents say this helps reduce health-care costs by decreasing the number of visits to physicians and dentists to treat chronic or recurrent illness, and eliminating the dispensing costs. Additionally, proponents argue that there is a concomitant decrease in the number of expensive laboratory tests performed.

Benefits of Switching

OTC products represent a significant source of additional revenue to pharmaceutical manufacturers. Sales increases of 400 to 500 percent or more during the first year a drug is available for

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Goals

The goals of this lesson are to explain how prescription drugs are switched to OTC status, and the major factors involved in decisions to do so. For the purpose of this lesson, the term switch refers to the legal reclassification of a drug from prescription-only (Rx) to nonprescription (OTC) status.

Objectives

At the conclusion of this lesson, the participant should be able to:

- Identify societal and economic factors that have helped popularize the Rx to OTC switch process.
- Identify how manufacturers, physicians, pharmacists, and consumers can benefit from a drug being switched from Rx to OTC status.
- Demonstrate knowledge of information to use in explaining how drugs were switched from Rx to OTC status under FDA's system of expert advisory panels.

self-therapy have been reported. For example, the year before topical hydrocortisone 0.5 percent became available for OTC use, it accounted for \$12 million in prescription sales. During its first year OTC, sales of \$70 million were recorded for the nonprescription products, with 75 percent of transactions in pharmacies. Interestingly, prescription sales of

topical hydrocortisone products that same year increased 50 percent, to \$18 million. Now that 1 percent hydrocortisone products are available, sales are even higher.

Patent protection is expiring over the next few years for some of the pharmaceutical industry's top sellers. Many of the nonsteroidal anti-inflammatory agents and histamine-2 antagonists are coming off patent. They will then be vulnerable to competition from generics. Switching a drug to OTC status extends its sales to over one-half million outlets without the barrier of a prescriber and dispenser, with no third-party payor forcing generic or therapeutic substitution, and with the advantage of mass media advertising.

Switching prescription drugs to OTC status is much more likely to bring significant financial returns to manufacturers than developing a new drug. The development process is estimated to take an average of 17 years at a cost of more than \$150 million. Also, hundreds of chemical entities are screened and tested to find one marketable drug.

With far less research and development costs, switching a proven prescription drug to the OTC market extends the active revenue producing years far beyond the patent expiration date. For example, a report from the OTC consulting firm of Kline & Company on the top 10 selling OTC drugs in 1991 showed the figures listed in Table 2.

Consumers benefit from the switch process because they have access to a wider variety of drug products. An analysis of consumer savings, financed by the Nonprescription Drug Manufacturers Association (NDMA - formerly the Proprietary Association), estimated that during the first three years of OTC availability of hydrocortisone products, the American public pocketed more than \$1 billion in savings including cost of physician services, waiting time in a physician's office, and prescription-associated expenses.

Proponents feel that compliance

may improve by increasing an individual's responsibility for his or her health care.

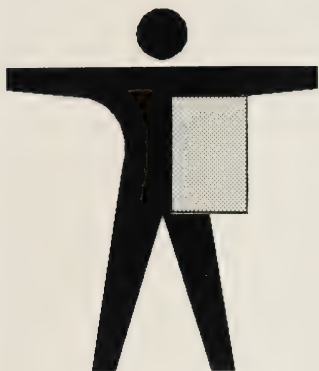
Physicians may also benefit by reducing the number of patients with trivial complaints and having more time for those with serious medical problems.

Each new OTC drug product affords an expanded counseling role for pharmacists.

Trends Contributing to Americans' Views on Self-Care

- Post World War II changes in values when people started to lose faith in organized health care systems.
- The focus on self care -- the "me generation" -- the heart of self-care.
- Emphasis on health and fitness.
- Believe in prevention and planning resulting from the revolution in values.
- Government deregulation with a political environment that favors self-care market development.
- Technology and consumer acceptance of it.
- Product development and improved packaging that fosters consumer acceptance of self-care.
- More organizations with a health agenda.
- Consumer demand for information.
- Self-care as a response to serious disease like cancer and AIDS, along with a national call for prevention.
- Aging population.
- Escalation of health care costs (\$675 billion in 1990, \$817 billion in 1992, and \$1.5 trillion estimated by 2000).

Table 1



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Program

- | | |
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| 8:30 am | Full Buffet Breakfast |
| 9:15 am | Continuing Education Seminar |

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Associate Professor, UMAB School of Pharmacy

Barbara Zuis, R.N.
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The cost of health care in the U.S. represents 11 percent of the gross national product (GNP) at the time of writing this lesson, and is expected to increase to 15 percent by the year 2000. The total expenditure for drugs in the U.S. in 1991 was \$40 billion, with \$28 billion for prescription drugs and \$12 billion for OTC products. Sales of OTC products are expanding at an annual rate of 6 percent, versus 1.5 to 2 percent for prescription drugs.

A World Health Organization survey reported that at least 40 million Americans take an OTC drug on any given day. Studies have shown that 65 to 85 percent of all medical care in the U.S. is for self-therapy, and OTC products are used by persons at all levels of socioeconomic status. At the same time, it is estimated that total spending for self-medication products accounts for less than two cents of the U.S. health-care dollar. According to the NDMA,

self-care is the largest, and least costly, component of the U.S. health-care system.

Legislation and OTCs

Before the 20th century, there were few restraints on the preparation, quality or availability of medication. Drug therapy consisted mainly of herbal or mineral formulations that gave palliative relief of symptoms, but did not treat disease. Laboratory and clinical research had not yet developed. There was no great need at that time for governmental regulations of drugs.

Food and Drugs Act. Federal regulation of drugs began with the Food and Drugs Act of 1906 in an effort to protect the public against unsafe drugs. The first comprehensive federal law to regulate drugs, the Food and Drugs Act, created the Bureau of Chemistry, predecessor to the current FDA. The

original Act has been amended significantly. Important dates of revision are 1938, 1951, 1962, and 1984.

Pure Food, Drug, and Cosmetic Act. In 1938, Congress enacted the Pure Food, Drug, and Cosmetic (FD & C) Act.

Before 1938, while the active ingredient needed proof of safety, the entire product did not. The first sulfonamide available in mass production was difficult to formulate. Suspension and syrups were extremely thick and difficult to shake into uniform distribution. What appeared to be a good idea, dissolving sulfanilamide in the solvent diethylene glycol to produce a pharmaceutically elegant clear solution, led to the death of over 100 people. Today, we know that diethylene glycol is a toxic solvent.

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Top Selling OTC Products in 1991

Product	Marketer	1991 Sales
Advil	American Home Products	\$285,000,000
Monistat 7	Johnson & Johnson	\$ 90,000,000
Sudafed	Burroughs Wellcome	\$ 81,000,000
Dimetapp	American Home Products	\$ 78,000,000
Motrin IB	Upjohn	\$ 74,000,000
Nuprin	Bristol-Myers-Squibb	\$ 74,000,000
Benadryl	Warner Lambert	\$ 73,000,000
Gyne-Lotrimin	Schering Plough	\$ 63,000,000
Actifed	Burroughs Wellcome	\$ 61,000,000
Afrin	Schering Plough	\$ 54,000,000

* All 10 products had been switched from prescription-only status.

Table 2

It required for the first time that manufacturers establish the safety of drug products including active and inactive ingredients which are shipped in interstate commerce, and that manufacturers properly label them. The labels were to list adequate instructions for use. Drugs considered safe for self-administration (OTC status) were to be labeled with complete instructions so that consumers could safely use the products without medical supervision.

While the Pure Food, Drug, and cosmetic Act clarified many issues omitted from the original law, there were still unsolved problems. For example, there was no clear delineation or legal distinction between drugs that required a prescription from those available without one. Manufacturers decided which drugs were to be limited to prescription, and which were suitable for self-therapy. The process was confusing since a drug could be limited to prescription by one manufacturer and classified OTC by another.

There was further confusion regarding how much and what type of information pharmacists should supply to a patient when prescriptions were dispensed or OTC products sold. FDA's decisions on

prescription/nonprescription status were also inconsistent and difficult to interpret.

Durham-Humphrey Amendment. To overcome these deficiencies, Congress passed the Durham-Humphrey Amendment to the Pure Food, Drug and Cosmetic Act in 1951. It set forth the specific statutory base for clearly separating drugs into one of two categories: prescription or non-prescription. The Durham-Humphrey Amendment specified three classes of drugs limited to prescription only use: (1) drugs that are unsafe for use except under the supervision of a licensed practitioner because of toxicity or other potential for harmful effect, or the method of use, or collateral measures necessary for use; (2) certain drugs listed by name in the Act that cause physical dependence; and (3) drugs limited to prescription order under a manufacturer's original New Drug Application (NDA). The Durham-Humphrey Amendment required that prescription drugs display the "federal legend" (Caution: Federal law prohibits dispensing without a prescription), and that prescription drug packages contain a package insert with specified product information for the prescriber. Also, authority over the labeling of OTC products was shifted from the Federal

Trade Commission (FTC) to the FDA. However, FTC retained control over advertising of OTC drugs.

Kefauver-Harris Amendment. As with the Pure Food, Drug and Cosmetic Act of 1938, the Kefauver-Harris Amendment resulted from a tragedy. In the late-1950s, the hypnotic thalidomide was developed.

It was believed, at that time, that laboratory experience on several species of pregnant animals that failed to demonstrate teratogenicity (birth defects) could be extrapolated to prove the drug was safe for use in pregnant women. Thalidomide showed that this is not true.

A number of women taking thalidomide delivered babies with severe birth defects. As a result, FDA was given extensive additional powers and the charge to assure that another thalidomide incident would never occur again.

The Kefauver-Harris Amendment to the Pure Food, Drug, and Cosmetic Act was legislated in 1962 and allowed for switching drugs from prescription to OTC status. This Amendment transformed the previous system of premarket clearance into one that required FDA to affirm that clinical studies of new drugs had demonstrated substantial evidence of effectiveness over placebo, as well as safety using the double-blind crossover system. The amendment required that drugs cannot be indicated for use in pregnant women or children until the safety of such use is proven.

It also required FDA to review all NDAs (new drug applications) approved since 1938 to assure those drugs also met the efficacy standards. Relating to OTC drugs, it gave FDA authority over labeling, and a monumental review of nonprescription drug products, most specifically their ingredients, and combinations with other therapeutic agents. The Durham-Humphrey Amendment required that OTCs be adequately labeled but did not provide the mechanism to do so. The

1962 legislation mandated that FDA undertake this function. It created a mechanism for the orderly, systematic evaluation of the prescription versus nonprescription status of existing medication.

Following enactment of the Kefauver-Harris Amendment, FDA contracted with the National Academy of Sciences/National Research Council (NAS/NRC) to evaluate drugs marketed between 1938 and 1962 for efficacy. The shortcoming of the evaluation was that only 420 of an estimated 500,000 commercially available OTC products were reviewed.

OTC Review Process

The solution to the problem began in 1972 when FDA convened 17 advisory panels of experts to review all OTC products for safety and efficacy for self-therapy. The panels were comprised of representatives from medicine, pharmacy and scientific communities as voting members, and consumers and industry representatives as non-voting members.

Among other assignments for these panels was the responsibility to identify prescription drug product ingredients which they believe, based upon personal review of available data, should be switched to OTC status.

When the review process was initiated in 1972, it was estimated that as many as 500,000 OTC products were marketed. Therefore, FDA directed the panels to investigate the body of knowledge on ingredients in OTC drug products. It had calculated that all of the products were comprised of 300 to 500 active ingredients. By the time the advisory panels concluded their work in the 1980s, they had studied over 700 ingredients encompassing more than 90 therapeutic categories, reported in more than 20,000 studies and other volumes of data and documents.

The review was divided into three phases. In Phase 1, the panels determined whether OTC product ingredients were safe and effective and correctly labeled for self-therapy. Ingredients were classified as: Category I (safe and effective for the proposed use), Category II (unsafe and/or ineffective), or Category III (insufficient data available to determine final classification). Each of the advisory panels' reports to FDA were published in the Federal Register at various times. In each instance, FDA requested comments to the panel reports.

In Phase 2, FDA reviewed the recommendations of the panels and the comments that had been submitted. The agency then published its conclusions as a tentative final monograph (TFM). Interested persons were again asked to submit comments or additional data.

Phase 3, which is still ongoing, consists of publication of Final Monographs. These establish standards for OTC product ingredients, labeling, and combining other therapeutic groups. When the review first started, drugs

in Category II could continue to be marketed until publication of the Final Monograph. Since then, FDA has dropped Category III status. In 1992, the agency was directed to finish the review quickly and remove all Category II ingredients from the market.

The review panels identified and recommended 40 prescription drugs and/or dosage strengths for transfer. The panels did not review every prescription drug. They reviewed only those which were suggested for consideration for OTC status, or those identified as appropriate for OTC use. A few are still under review by FDA, but further impetus on switches from prescription to OTC will be based on submissions of New Drug Applications in the same manner as prescription drugs.



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Board of Pharmacy Examination

Answers to the 1905 Exam

Richard D. Baylis, P.D., Director, Mid-Atlantic DUR, Inc.

A. Pharmacy Section

1. a. The U.S.P. stands for the United States Pharmacopeia. It is published every 10 years by a committee of the U.S. Pharmacopeial Convention. Its purpose is to compile a compendia of currently used medications with standards for manufacture and doses.
- b. A "liquor", by USP standards, is an aqueous solution of some medicinal agent.
- c. Mucilage of Acacia

Acacia	340 Gm
Lime Water	330 Gm
Water qs	1000 Gm

Wash the acacia with cold water and allow to drain. Add Lime Water to it, and enough water to make the mixture weigh 1,000 Gm. Agitate or stir it occasionally until the Acacia is dissolved, and strain. Keep in well stoppered, completely filled bottles, in a cool place.

d. Mucilage of Tragacanth

R	Tragacanth	6 Gm
	Glycerin	18 Gm
	Water qs	100 GM

Mix glycerin with 75cc water in a tared vessel, heat the mixture to boiling, add the Tragacanth, and macerate during 24 hours, stirring occasionally. Then add enough water to make the mixture weigh 100 Gm, beating it until it has a uniform consistency, and strain it forcibly through muslin.

2. a. A Glycerite is a solution of a medicinal substance in glycerin.
 1. Glycerite of Tannic Acid
 2. Glycerite of Amyli
 3. Glycerite of Boroglycerin
- b. Glycerite of Starch is a translucent jelly formed by adding starch to glycerin and heating the mixture until a jelly forms. Glycerite of Starch is used as an emollient and an ointment or lotion base.

- c. An emulsion is a liquid preparation in which oleaginous substances are suspended in aqueous fluids by the intervention of Gum or other viscid matter.
- d. Emulsions are classified by the type of suspending agent used.

B. Toxicology

1. Doses

Mercurous Iodide	10 mg (1/5 gr)
Mercuric Iodide	3 mg (1/20 gr)
Mercurous Chloride - laxative	125mg (2 gr) or
alterative	65mg (1gr)
Mercuric Chloride	3mg (1/20gr)
Chloride of Gold	5mg (1/10gr)
2. Black Drops
Official name is Vinegar of Opium

R	Granulated Opium	100 Gm
	Powdered Myristica	30 Gm
	Sucrose	200 Gm

Macerate in 500 ml diluted acetic acid for 7 days. Percolate with enough diluted acetic acid to make 1000ml of percolate. There is 900 mg of morphine per ounce.
3. Antidotes

Face Bleach (Ammoniated mercury). Use an emetic of zinc sulfate (20 gr) or mustard (2 tsp).

Creosote No known antidote. Use mucilaginous drinks and stomach pump.

Rough on Rats (Arsenic). Use an emetic of zinc sulfate (20 gr) or mustard (2 tsp) and Ferri Hydroxidum cum Magnesii Oxido - 1/2 tumblerful.

Hair Dyes - Pyrogallol - emetic; Zinc sulfate (20gr) followed by Magnesium sulfate (2 tabspfl), then with Mucilage of Acacia (2tabspfl).

Indelible Ink (silver nitrate & ammonia) - Vinegar (1-2 tablespoonsful), dilute with equal amount of water (for the ammonia) and supportive therapy (for the silver nitrate).

Embalming Fluid (formaldehyde). Use an emetic of zinc sulfate (20 gr) or mustard (2 tsp) and Aromatic Spirits of Ammonia (1 tsp).

4. Opisthotonos - a tetonic spasm, in which the body is arched backwards, so that it rests on the head and heels (symptom of strychnine poisoning).
Asphyxia - the condition that supervenes on the interruption of respiration.
Clonic spasms - spasmodic movements which are of short duration, and alternate with periods of relaxation.
Syncope - a state of suspended animation, due to sudden failure of the action of the heart (a faint).
Catalepsy - a disease of the nervous system, characterized by attacks of powerlessness, commonly with the loss of consciousness, accompanied by a peculiar form of muscular rigidity, in which the limbs remain for a time in the position in which they are placed.
5. Dose for 1 year old = X/13
Dose for 3 year old = 3X/15
Dose for 7 year old = 7X/19
Dose for 11 year old = 11X/23
Dose for 13 year old = X
6. Symptoms of poisoning include a warming sensation in the stomach, sometimes with nausea but usually without vomiting, with slowing pulse and respiration, the skin is cool and moist and there is profound prostration. Numbness and tingling is first felt in the lips and mouth followed by the fingertips. Dimness of vision, with either contracted or dilated pupils, and occasionally delirium and stupor or convulsions preceding death. Treat by keeping the patient in a horizontal position or with the feet high than the head. Empty stomach with stomach pump. Circulatory stimulants may be used, such as strychnine, ammonia, and atropine, hypodermically. Keep body warm.
7. Fluid Extract Indian Hemp is Fluidextractum Cannabis Indicae. Dose is 0.05 cc (1 minim)
Croton Oil is Oleum Tigli. Dose is 0.05cc (1 minim)
Extract Calabar Bean is Extractum Physostigmatis. Dose is 8 mg or 1/8 grain.
Dog Button is Nux Vomica. Dose is 100 mg or 1 1/2 grains.
Henbane is Hyoscyamus. Dose is 130 - 320 mg or 2-5 grains of whole leaves.
8. The official name of the alkaloid from Nux Vomica is strychnine. Strychnine occurs in colorless, transparent, prismatic crystals, or as a white crystalline powder; odorless; permanent in the air. The maximum dose is 3mg (1/20gr). For poisoning, keep patient quiet, *do not* empty stomach. A solution of potassium permanganate should be used to counteract the alkaloid. Chloroform may be used for the convulsions. After the convulsions have subsided, chloral

hydrate or potassium bromide may be used to continue sedation. Amyl nitrate may be used hypodermically for respiratory distress during the convulsions.

9. Digitalis - 65 mg or 1 grain
Belladonnae Folia - 65 mg or 1 grains
Oleum Gaultheriae - 1 cc or 15 minims
Colchicum - 250 mg or 4 grains
Stramonium - 65 mg or 1 grain

C. Pharmacy Practice

3. a. The strength of medicated vinegars is 10%.
b. There are two official vinegars in the USP 8th Edition. They are Vinegar of Squill and Vinegar of Opium. (Another official vinegar is also from that time period, Vinegar of Colchicum, but we do not know in which edition of the USP it was listed.) Vinegars are made by maceration of the active ingredient with dilute acetic acid.
- c. Hydroalcoholic tinctures are preparations made of active ingredient and a pre-determined proportion of alcohol and water. The alcohol is used to extract the active principals of the ingredient and the water is used as a diluent. In some instances the water is used as a menstruum.
- d. An ethereal tincture is one in which the extraction process uses ether. The ether dissolves oleaginous material and then is evaporated off.
4. a. Alcohol 60% and Solution of Ammonia are the menstruum for an ammoniated tincture.
b. Officially, red and white wine contained 10% alcohol (USP VIII). But pharmacists in the U.S. used port and sherry wines which are fortified and contained over 20% alcohol.
c. Tannin is tannic acid usually obtained from nutgalls. Tannin is a yellowish-white to light brown, amorphous powder, gradually turning darker when exposed to light and air, usually cohering in the form of glistening scales or spongy masses, odorless, or having a faint, characteristic odor, and a strongly astringent taste.
- d. Glycerin, water and alcohol are three tannin solvents.
5. a. Antimonial Powder is known as James's Powder and is officially named Pulvis Antimonialis (USP VII).
Antimonial Powder
Antimonious Oxide 25 gram
Calcium Phosphate 50 gram

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b. Aromatic Powder

Saigon Cinnamon	35 gram
Jamaica Ginger	35 gram
Cardamon Seed	15 gram
Myristica, grated	15 gram

c. Pulvis Cretae Compositus

Prepared chalk	30 gram
Acacia, fine powder	20 gram
Sugar, fine powder	50 gram

d. Pulvis Effervescens Compositus
(Seidlitz Powder)

R Blue Paper

Sodium Bicarbonate	35 Gm
Potassium Tartrate	45 Gm
Sodium Tartrate	45 Gm
Mix and make 12 powders	

R White Paper

Tartaric Acid	26 Gm
Make 12 powders	

6. a. Sublimed sulphur is a slightly gritty powder of a bright greenish-yellow color. Odorless and tasteless. Microscopically it is seen to consist of irregular angular particles mixed with almost opaque globules.
- b. It is used internally (up to 50 grains) as a laxative, chronic rheumatism and gout, chronic bronchitis and asthma, and amoebic dysentery. Externally it is used in ointments and lotions (5 to 20%) for scabies, ringworm, acne, psoriasis, etc.
- c. Washed Sulphur

R Sublimed sulphur	100 gram
Ammonia Water	10 ml
Water qs	

Pass the sublimed sulphur through a No. 30 sieve, mix it thoroughly with 100ml of water, add the ammonia water, and set the mixture aside for three days in a closed vessel, agitating occasionally. Then add 100ml water, transfer the mixture to a strainer, and wash the sulphur with water until the washings cease to impart a blue color to red litmus paper.

The ammonia water is used to remove any traces of sulfuric acid from the finished product.

- d. Because it is free from acidity and this prevents the sulphur from caking.
7. a. There are two official pill masses - Ferrous Carbonate and Mercury.
- b. Confections are soft solids, in which one or more medicinal substances are incorporated with saccharine matter, with a view either to their preservation or more convenient

administration.

There are two official confections - Rose and Senna.

- c. Medicinal substance 10 gram
Sugar of Milk 90 gram
Mix thoroughly until a fine powder results.
- d. Trituration of Elaterin is official.

8. a. Cerates are unctuous substances consisting of oil or lard, mixed with wax, spermaceti or rosin, to which various medicaments are added. Cerates are made with wax and the latin word for wax is cera.
- b. There are six official cerates.
- c. The Latin official name is Ceratum.
- d. Camphor Cerate

R Camphor Liniment	100 gram
White Wax	350 gram
White Petrolatum	150 gram
Benzoinated Lard	400 gram

Melt the White Wax, add the White Petrolatum, then the Benzoinated Lard, and continue to heat until the mixture is liquified. While the mixture is cooling, add the Camphor Liniment, and incorporate thoroughly by stirring until it congeals.

9. a. The Latin official name is Adeps Benzoinatus.
- b. Benzoinated Lard

R Lard	1000 gram
Benzoin	20 gram

Add the Benzoin to the Lard and mix thoroughly; then melt the Lard by means of a water-bath, and, stirring frequently, continue the heat for two hours, covering the vessel and not allowing the temperature to rise above 60°. Lastly, strain the liquid through muslin and stir occasionally while it cools. In warm weather, replace 5% or more of the Lard with White Wax.

- c. Pepsin is a mixture containing a proteolytic ferment or enzyme, obtained from the glandular layer of the fresh stomach of the hog.
- d. Pepsin digests not less than 3,000 times its own weight of freshly coagulated and disintegrated egg albumen.
10. The Bichloride of Mercury will precipitate the alkaloids from the Elixir of Calisaya (Elixir of Cinchona Alkaloids N.F.)

D. Chemistry

1. a. Specific gravity is the ratio of the weight of an equal bulk of a standard substance. The substance taken as a standard is water for solids and liquids, and air for hydrogen gases.
b. Benzoic Acid, Hydrochloric acid, and Hydrofluoric acid.
a. Sulphuric acid is 94% and the SpGr = 1.83
2. a. Potassium - Violet
b. Sodium - Yellow
c. Lithium - Crimson
d. A radical is a group of atoms that act as a unit, but commonly do not exist in the free state.
e. Qualitative analysis is the determination of the elements that compose a substance.
Quantitative analysis is the determination of the amount of an element or compound in a substance.
3. a. Bi. - Two atoms or equivalents of the constituent.
Sub. - The lower of two compounds of the same element or basic.
Per. - The highest valence of a series.
Hypo. - Acids and salts having the last number of atoms of oxygen in a series of compounds of the same elements.
b. Acids, hydrocarbons and bases.
4. a. Boric acid and Sodium Borate
b. Lithium Benzoate, Lithium Bromide, Lithium Carbonate, Lithium Citrate, Lithium Citrate Effervescent, Lithium Salicylate.
All may be prepared from Lithium Carbonate.
5. a. Sodium Acetate -- Acetic Acid + Sodium Carbonate
Sodium Benzoate -- Benzoic Acid + Sodium Carbonate
Sodium Salicylate -- Salicylic Acid + Sodium Carbonate
b. Carbon dioxide is released and sodium tartrate is formed.
6. a. Ammonia gas is obtained by the action of lime on Ammonium chloride.
Ammonium Hydrate - is solution of ammonia and water.
Ammonium chloride - is produced from the gas liquor found in the condensing vessels of coal gas works and the ammonia liquor called bone spirit from the destructive distillation of bones for making bone black.
Ammonium carbonate - is made by subliming a mixture of either Ammonium chloride or sulphate with chalk. The chalk and Ammonium chloride are sublimed in earthen or leaded containers.

Ammonium acetate - is made by treating Ammonium carbonate with diluted acetic acid.

7. a. The principal compound of silver is silver sulphide.
b. Silver nitrate, mitigated (33.3%), Silver nitrate, molded (95%), Silver oxide
c. Nitric and hydrochloric acids
d. Fuming nitric acid and sulphuric acid are added to glycerin under cool conditions.
8. K^+ ; Potassium is obtained by decomposing Potassium carbonate, mixed with charcoal, in a covered crucible. Potassium is a solid, soft, ductible substance, easily cut with a knife and of a silver-white color.
Potassium acetate, bicarbonate, bitartrate, bromide, carbonate, chlorate, citrate, cyanide, dichromate, ferrocyanide, hydroxide, hypophosphate, iodide, nitrate, permanganate, and sulphate are the official compounds.
9. Sulphonethylmethane - Trional
Sulphonmethanum - Sulphonal
Phenylis Salicylas - Salol
Methylthionae Hydrochloridum - Methylene Blue
Hexamethylenamina - Methenamine
10. $MgBr_2 + 2Cl = MgCl_2 + Br_2$
 $K_2CO_3 + CO_2 + H_2O = 2KHCO_3$
 $2NH_4Cl + Ca(OH)_2 = CaCl_2 + 2NH_3 + 2H_2O$

The common names are:

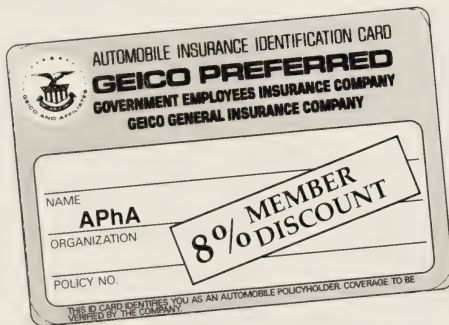
$CHCl_3$ - Chloroform
 CHI_3 - Iodomethane

E. Materia Medica

1. *Synonym:* Pleurisy root
Components: Asclepiadin, asclepin and a volatile oil
Properties: Diaphoretic, emetic and cathartic
Official Preparation: Fluidextract Asclepias
Dose: 2 cc (40 minims)
2. *Synonym:* Deadly Nightshade Root
Components: Atropine
Properties: Anodyne, antispasmodic, checking secretions, narcotic and mydriatic.
Official Preparation #1: Fluidextract Belladonna Root
Dose: 0.05 cc (1 minim)
Official Preparation #2: Belladonna Liniment
3. *Synonym:* Yellow Jasmine Root
Components: Gelsemine, Gelseminic acid
Properties: Neuralgias, of the facial nerves
Official Preparation #1: Extractum Gelsemii
Dose: 8 - 16mg (1/8 - 1/4 gr)
Official Preparation #2: Fluidextract Gelsemii
Dose: 0.06 - 0.2cc (1 - 4 minims)

- Official Preparation #3: Tincture Gelsemi*
Dose: 0.3 - 1.3cc (5 - 25 minims)
4. *Synonym: Mandrake, May Apple*
Components: Podophyllotoxin, Picropodophyllin
Properties: Drastic cathartic
Official Preparation #1: Fluidextractum Podophyllii
Dose: 0.3 - 0.9 cc (5-15 minims)
Official Preparation #2: Resina Podophyllii
Dose: 8 - 16mg (1/8 - 1/14 gr)
Official Preparation #3: Extractum Podophyllii
Dose: 15 mg (1/4 gr)
5. *Synonym: Colchicum Root*
Components: Colchicine
Properties: Gout
Official Preparation #1: Extractum Colchici Cormi
Dose: 16 - 65mg (1/4 - 1 gr)
Official Preparation #2: Fluidextract Colchici Cormi
Dose: 0.2 cc (4 minims)
Official Preparation #3: Vinum Cochici Cormi
Dose: 0.6 - 2.5cc (10 - 50 minims)
6. *Synonym: Squill*
Components: Scillipicrin, Scillin, Scillitoxin
Properties: Diuretic
Official Preparation #1: Acetum Scillae
Dose: 1 cc (15 minims)
Official Preparation #2: Fluidextract Scillae
Dose: 0.1 cc (1 1/2 minims)
Official Preparation #3: Syrupus Scillae
Dose: 2 cc (30 minims)
Official Preparation #4: Syrupus Scillae Compositus

- Dose: 2 cc (30 minims)*
Official Preparation #5: Tinctura Scillae
Dose: 1cc (15minims)
Official Preparation #6: Pilulae Digitalis, Scillae et Hydrargyi
Dose: 1 pill
7. *Synonym: Wild Cherry Bark*
Components: Amygdalin
Medical Properties: Cough
Official Preparation: Syrupus Pruni Virginianae
Dose: 10 cc (2 1/2 drams)
8. *Synonym: Blue Gum Leaves*
Components: Eucalyptol
Medical Properties: Cough, and smoked leaves for bronchitis or asthma
Official Preparation: Fluidextractum Eucalypti
Dose: 2 cc (30 minims)
9. *Synonym: Senna*
Components: Aloe-emodin, Anthraglucosennin
Medical Properties: Cathartic
Official Preparation #1: Fluidextractum Sennae
Dose: 2 cc (30 minims)
Official Preparation #2: Infusum Sennae Compositum
Dose: 60 cc (2 oz.)
Official Preparation #3: Syrupus Sennae
Dose: 8 cc (2 dr)
Official Preparation #4: Pulvis Glycyrrhizae Compositus
Dose: 4 Gm (60 gr)



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Mail Order Pharmacy

A. Teresa Melson, UMAB School of Pharmacy Student

This article is the second in a series written by pharmacy students in the first course of the new entry-level Pharm.D. program at the University of Maryland School of Pharmacy, PHAR 516 (Pharmacy Practice and Education) is an introductory course which exposes the students to pharmacy practice, pharmaceutical sciences, ethics, communication, and critical thinking. One of the class assignments was to write a critical evaluation on one of three topics: pharmaceutical care, pharmacy technicians, or mail-order pharmacy. This course was developed by MPhA Past President Ilene Zuckerman with the assistance of MPhA member and graduate student Diane McNalley.

From 1980 to 1986 there was an 80% increase in prescription drug prices.¹ With increasing emphasis being placed upon curbing the escalating costs of prescription drugs, the services provided by mail-order pharmacies have become a competitive, yet controversial, alternative to community pharmacy.

Mail-order pharmacies allow a patient the convenience of mailing in their prescription and having their medications delivered to their home within days. Revenues from services of this type have increased by 50% annually since 1981, from less than \$100 million to \$750 million in 1986.² It is estimated that mail-order pharmacies service 10% of the prescription drug market.³

Although the rapid increase in mail-order pharmacy use is undisputed, there has been much debate concerning the advantages and disadvantages of this type of service. However, it has been concluded that mail-order pharmacy is effective in providing a viable alternative to community pharmacy for the delivery of maintenance or chronic medications to the elderly.

A study mandated by the Medicare Catastrophic Coverage Act of 1988 indicated that 57% of mail-order pharmacy total sales were to patients who were over the age of sixty-five. This may be attributed to the fact that maintenance drugs, which are a significant market for mail-order pharmacy, are often prescribed for the elderly patient.⁴

A primary incentive for the use of mail-order pharmacy is lower pricing of prescription drugs. Pricing is an important factor, particularly when considering the elderly patient, who

quite often is on a fixed income, but is prescribed the greatest percentage of maintenance medications.

A study of third-party providers reported a 25% reduction in medication costs when using mail-order services. Recipients were charged \$2 per prescription, as compared to a \$5 co-payment per prescription at a community pharmacy.⁵

University employees using mail-order service indicated cost as a primary reason for their choice. The co-payment for mail-order was \$5 for generic drugs and \$10 for brand-name products and there was no deductible. However, the same drugs obtained under their former major medical plan required a \$200 deductible and a 20% coinsurance.²

A study of employers reported savings from 5-50% when using mail-order services in the quality of service between the two types of pharmacies.

The fact that mail-order pharmacy is easily accessible is very important when considering the elderly patient. For those patients who are physically impaired or do not have access to transportation, the convenience of home delivery of prescription drugs is quite beneficial.

Typically, the community pharmacy dispenses a one-month supply of chronic medications, whereas mail-order service dispenses a three-month supply of the same medications. Instead of having to visit the local pharmacy once a month to refill their prescriptions, a patient need only walk to his mailbox once every three months and pick up his medications.

Although mail-order pharmacy offers advantages such as reduced pricing and the convenience of home delivery, there has been much debate

as to its disadvantages. The primary area of contention relates to patient counseling. With the role of the pharmacist becoming more and more focused on patient education, counseling, and physical assessment, the fact that mail-order pharmacy provides no face-to-face interaction between the patient and the pharmacist has been criticized.

The American Pharmaceutical Association cites several services which are provided by a community pharmacist that may not readily be available through mail-order pharmacy including monitoring patients for adverse side effects and drug interactions, providing non-prescription drug use consultation, performing triage, and providing physicians with immediate feedback when necessary.

The pharmacists, being the most knowledgeable health care professional regarding drug usage is best qualified to providing a patient with necessary information relating to the purpose of a particular drug, possible adverse side effects, proper storage and administration. This is accomplished most effectively through face-to-face consultation with a patient.

Although a 24-hour toll free telephone consultation service is provided for patients using mail-order pharmacies and written information relating to the prescribed drug is provided for patient use, there is no face-to-face consultation between the pharmacists and the patient.

A Food and Drug Administration study supports the contention that telephone consultation service provided by mail-order pharmacies is as effective as consultation with a local pharmacist for the management of therapeutic problems. It also feels that the lack of personal contact with the local pharmacist does not negatively affect consumer welfare.⁷

The American Medical Association indicates that 80% of all mail-order pharmacy prescriptions are written for drugs used in the maintenance of chronic disease.⁵ In the case of maintenance or chronic medications which are being prescribed to patients who have initially been adequately informed about all aspects relating to their medication and its proper usage, the lack of face-to-face consultation with a pharmacist should not present a problem. However, the patient must maintain regularly scheduled visits to his physician and be aware of any new side effects or complications which he has not previously experienced.

However, a patient who has been prescribed a new medication, for which he has no prior knowledge or information, would greatly benefit from direct face-to-face consultation with a local pharmacist. Through direct interaction and patient assessment, the pharmacist can be certain that the patient fully understands information relating to the specific drug and instructions for its proper use. Receiving written information along with your drug through the mail would provide the patient with drug information, but there is no certainty that the patient understands what he has read.

Drugs used in the treatment of acute, short-term illnesses and non-prescription drug items often are not available through mail-order service. It is then necessary for the patient to use the services of the community pharmacy as well. Concern is warranted in this situation. Each pharmacy will have their patient records. However, each will be incomplete, increasing the chances that adverse drug interactions may occur between all medications dispensed. This problem may be alleviated if the prescription drugs he has received from mail-order service. The pharmacist may then check for possible drug interactions before the drug is dispensed.

Quality control and safety are factors that have been criticized in relation to mail-order pharmacy. Although the National Association of Boards of Pharmacy have approved rules and regulations that states may adopt to regulate mail-order pharmacy including licensing, record keeping, patient-pharmacist communication, labeling, and shipping,⁸ fewer than 50% of states currently regulate this service.⁹

Despite these concerns, studies have found mail-order pharmacies to be as safe as community pharmacies. Studies have shown no higher drug-dispensing error rates through mail-order service when compared to community pharmacy.¹

Although face-to-face interaction between the pharmacist and the patient in patient assessment and education, mail-order pharmacy is becoming a viable option to community pharmacy in specific cases.

The American Medical Association considers mail-order pharmacy to be appropriate for long-term, chronically ill patients who have received adequate information relating to their medications.⁵

Although there are legitimate criticisms of mail-order service relating to pharmacy, the quality of its products and services have been found to be similar to those of the community pharmacy. This fact, coupled with the convenience and lower pricing associated with mail-order pharmacy is appealing to an increasing number of patients.

An area needing to be addressed further in relation to mail-order pharmacy is that of regulation. The percentage of states adhering to regulation currently is unacceptable. Regulation should be required for all mail-order pharmacies, as they are for all community pharmacies. There should be no distinction between the two types of operations since each dispenses drugs to the patient and each may literally be responsible for the life or death of the patient. R

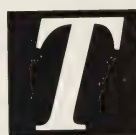
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Recent Industry Law Suits and Verdicts

*David Carrera, Director, Annual Programs and Alumni Relations
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In case you haven't heard, David took on Goliath and won. In October, an Arkansas State judge ordered Wal-Mart Stores, Inc. to stop selling pharmaceuticals, health and beauty aids below cost in Conway, Arkansas.

Three independent pharmacies had sued the world's largest retailer accusing it of selling items below cost to lure away the independent pharmacies' customers. The judge ordered Wal-Mart to pay \$289,000 in damages. The suit sought damages of \$1.1 million.

The ruling effects Wal-Mart pricing policy only in Conway, Arkansas; however, it could encourage smaller retailers in other areas to sue larger competitors in an effort to end the policy of loss leaders. Loss leaders are items sold at or below cost but, because they help generate traffic in stores, help increase overall sales.

Legal experts have said that the Arkansas statute is far more specific than federal antitrust law. This has raised doubts that this case would have help up in federal court.

Recently, a Wal-Mart store opened in York, Pennsylvania about 25 miles north of the Maryland border. According to one independent pharmacy owner in northern Baltimore County, to celebrate its grand opening, the retailer offered \$15.00 coupons good on prescriptions to anyone who walked through the doors during its first week of business. In doing so, it has been estimated that the store established a pharmacy customer base of more than 4,000 by the end of its first week of operation.

In a separate case, also in October, three of the nation's biggest drugstore

chains filed a broad antitrust lawsuit accusing seven drug manufacturers of conspiring to mark up prices they charge to pharmacies, often up to 1,200 percent more than they do to other customers such as HMO's and hospitals.

The mail order giant Medco Containment Systems, who recently was purchased by Merck, was also sued, accused of inducing discounts from drug manufacturers.

Antitrust experts said the case could take years to resolve and will be hard to prove. For the suit to be successful, it must be established that the pricing policies reduced competition and, as a result, the plaintiffs' business had been damaged.

Among the three leading chains, other small chains as well as ten independent pharmacies in Minnesota joined the lawsuit.

In early November, five class action lawsuits were filed in U.S. District Court in New York by the Texas based Pharmacy Freedom Fund. Twenty-four manufacturers and six wholesalers are alleged to have established discriminatory pricing policies. The suits are asking for damages that could exceed \$33 billion. **R**

English Only Warnings Adequate on OTC's

David B. Brushwood, J.D.



The allegations in a recent California case are that a child contracted Reye Syndrome as the result of using baby aspirin manufactured by the defendant. In March, 1986, when he was less than four months old, the child exhibited symptoms of a cold or similar upper respiratory infection. To relieve these symptoms, the child's mother gave him baby aspirin. The child developed Reye Syndrome, resulting in severe neurological damage, including cortical blindness, spastic quadriplegia, and mental retardation.

The label and the package insert of the baby aspirin used by the mother contained ample warnings relating to the risk of Reye Syndrome, all of which were printed in the English language. At that time, the mother was literate only in Spanish. Because she could not read English, the mother was unable to read the warnings on the baby aspirin label or package insert.

The subsequent lawsuit alleged that the manufacturer was negligent in failing to include Spanish language warnings on the package of baby aspirin. There was evidence that the manufacturer had promoted use of its product in Spanish language advertisements, but no evidence that these advertisements had led to the mother purchasing the product.

The court examined FDA requirements for labeling and discovered a notice in the Federal Register stating that the agency "encourages the preparation of labeling to meet the needs of non-English speaking or special user populations as long as such labeling fully complies with agency regulations." But the controlling language required only that manufacturers provide full English labeling for all nonprescription drugs except those distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English. California state laws paralleled this requirement.

The court held that under these circumstances a manufacturer could not be held liable for failing to provide a Spanish language warning. The court noted that specifics of product labeling are best determined by legislatures and administrative agencies, not courts of law. In the absence of a statute or regulation that required Spanish language labeling, the court felt it best not to establish a new rule for such labeling. **R**

Based on *Ramirez v. Plough, Inc.*, 1993 Westlaw 503508 (Cal. December 9, 1993).

About the Author

David Brushwood is Professor of Pharmacy Health Care Administration at the University of Florida. His articles on cases affecting pharmacists and pharmacy are provided as a courtesy to state pharmacist associations. Questions on legal issues affecting Maryland practice should be directed to your legal representative or the Maryland State Board of Pharmacy. Copyright 1994, David B. Brushwood. All Rights Reserved. Reprinted from *Dickinson's Pharmacy*, January, 1994.

Continuing Education

Continuing Education Quiz

February 1994 -- OTC Switches

This month's questions are taken from the article on President Clinton's health reform proposal in this issue. Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$30 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by July 31, 1994. A continuing education certificate for three contact hours (three credits) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

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1. The legislation that differentiated prescription from nonprescription drugs is the:
 - a. Pure Food, Drug and Cosmetic Act.
 - b. Waxman-Hatch Act.
 - c. Durham-Humphrey Amendment.
 - d. Kefauver-Harris Amendment.
2. All of the following statements about the sales of topical 0.5 percent hydrocortisone its first year as OTC are true except:
 - a. OTC sales amounted to \$70 million.
 - b. Rx sales amounted to \$18 million.
 - c. 75 percent of OTC sales were in pharmacies.
 - d. Rx sales decreased 50 percent that year.
3. Studies have shown which range of all medical care in the U.S. is for self-therapy?
 - a. Less than 25 percent
 - b. 25-45 percent
 - c. 45-65 percent
 - d. 65-85 percent
4. The legislation that resulted from the sulfanilamide elixir tragedy was the:
 - a. Pure Food, Drug and Cosmetic Act.
 - b. Waxman-Hatch Act.
 - c. Durham-Humphrey Amendment.
 - d. Kefauver-Harris Amendment.
5. The leading selling OTC product in 1991 was:
 - a. Actifed.
 - b. Advil.
 - c. Afrin.
 - d. Benadryl.
6. Which of the following statements about the FDA OTC Advisory Panels is true?
 - a. All OTC ingredients not proven to be both safe and effective had been removed from the market by 1992.
 - b. The impetus for future switches from Rx to OTC status will be based on the panels' findings.
 - c. The panels reviewed over 700 ingredients encompassing more than 90 therapeutic categories of drugs.
 - d. Every prescription drug was reviewed for potential switch to OTC status.
7. A major concern about the escalation in the cost of health care in the U.S. is that it:
 - a. already accounts for 5 percent of GNP.
 - b. already accounts for 8 percent of GNP.
 - c. already accounts for 11 percent of GNP.
 - d. already accounts for 15 percent of GNP.
8. The legislation that resulted from the thalidomide tragedy was the:
 - a. Pure Food, Drug and Cosmetic Act.
 - b. Waxman-Hatch Act.
 - c. Durham-Humphrey Amendment.
 - d. Kefauver-Harris Amendment.
9. The thalidomide tragedy resulted from the drug causing?
 - a. addiction.
 - b. cancer.
 - c. deaths.
 - d. teratogenicity.

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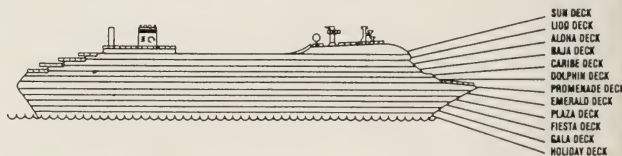
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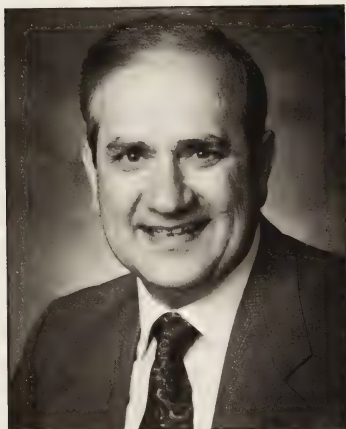
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President's Commentary

Howard Schiff, P.D.



In the popular musical "Fiddler on the Roof," the lead character Tevye, decries the loss of tradition in the opening song and throughout the show. He defines tradition as doing something the way it's always been done simply because that's the way it's always been done. He spends much of the show weighing the benefits of breaking a tradition for the happiness of his daughters, his wife, and his village. Somewhere, somehow, Tevye seeks to find a balance between tossing away generations of tradition and the demands of a changing world.

So it is in pharmacy today in the state of Maryland. For as long as anyone can remember MPhA annually presented the Governor with a list of three candidates for the Maryland State Board of Pharmacy from which the Governor chose one -- usually the first name on the list which was the Association's preferred candidate.

There has always been a sincere effort by MPhA and its Nominating Committee to ensure that all facets of the profession were represented. State Board seats had *informal* recognition as independent, chain, or hospital seats with consideration of a person's geographical or minority status as a sort of sub-designation. Candidates presented to the Governor were carefully chosen; generally these people were someone with plenty of experience because, after all, the Board has to establish "rules and regulations that are necessary to protect the public health, safety, and welfare and establish standards for practicing pharmacy and operating pharmacies..."

In the last two years, however, that tradition has been broken. The Maryland General Assembly decided to open up the process, with, I'm sure, the best of intentions. The law now states that MPhA shall "notify all licensed pharmacists in the state of the vacancy to solicit nominations to fill the vacancy and conduct a balloting process where every licensed pharmacist is eligible to vote to select the names of the licensed pharmacists that will be submitted to the Governor."

What does all this mean? Certainly the annual list of recommendations for the Board of Pharmacy has now passed in large part from the hands of MPhA to the pharmacist community at-large. The process may disintegrate into a popularity contest. The MPhA will oversee the nominating and balloting process and make an effort to keep the balance and quality on the Board by allowing candidates to address members of the MPhA at our Mid-Year meeting and by providing pharmacists with information on each candidate.

Ultimately, it is still an appointment controlled by the Governor. He or she, according to the law, can still appoint whomever he or she pleases. Moreover, this is not a burning issue with everyone holding their collective breaths waiting for the list of nominees.

But it is important. Any group that establishes rules by which we practice holds our future in their hands. It seems as though the Board has and continues to work well using the old appointment process. However, the new rules leave everything so wide open that anything can happen. On the other hand, perhaps I am underestimating the democratic process. Now I'm beginning to sound like Tevye.

Let's just say this is one tradition we may all have to rethink.

R

Advising Patients on "Switch" Drug Products

Part II: Counseling on Systemic Drugs Switched from Prescription

Thomas A. Gossell, R.Ph., Ph.D., Dean, Ohio Northern University

J. Richard Wuest, R.Ph., Pharm.D., Professor of Pharmacy, University of Cincinnati



Before 1972, prescription drugs were switched to OTC status by manufacturers or other interested persons filing a petition with FDA requesting the change. Some examples include chlorpheniramine (in Coricidin), acetaminophen, dextromethorphan, and tolnaftate. A massive review of OTC drug product ingredients and indications was initiated in 1972. The word *massive* describes the process accurately because the review was the largest undertaking ever conducted by FDA. The review covered 58 pharmacologic groups with over 800 active ingredients claimed to be effective for over 2000 indications. The total number of products on the OTC market at that time has been estimated to exceed one-quarter million dosage forms and strengths.

The major purpose of the review was to assure that every OTC drug on the market at that time was safe and effective for self-therapy. Among other assignments given to FDA was to identify prescription drug product ingredients which might be suitable for self-medication.

To undertake these tasks, FDA assembled panels of experts to determine whether OTC drug product ingredients were safe for self-therapy. The panels' reports to FDA were published in the Federal Register, and comment were requested from interested parties.

After receiving the comments, FDA reviewed each suggestion and published its conclusions as Tentative Final Monographs (TFM) in the Federal Register. Interested persons

were permitted to submit additional data or to comment.

FDA then reviewed the comments. After reaching its conclusions, the agency published the Final Monograph on each particular category of OTC drugs under review. The final Monographs become the established standards for OTC products' active ingredients, claims and labeling.

This review has taken longer than was originally anticipated due, in large extent, to the fact that while OTC ingredients had been established as safe, their efficacy had not been proven using the methods that were required for prescription drugs by 1972. While it was anticipated that the project would take less than 10 years, more than 20 years later the final monographs have still not been published for some drug categories.

During the last two decades, as a result of this review, several dozen drugs have been switched from prescription to OTC status. These include topical agents such as antipruritics, antiscaly agents, antifungal, nasal decongestants, ophthalmic vasoconstrictors and drugs used to treat dermatitis, seborrhea, psoriasis and lice. Orally ingested drugs include analgesics, antihistamines, decongestants, anthelmintics and antidiarrheal remedies. Table 1 summarizes the systemic drugs and dosage forms that have been switched from Rx to OTC status.

The impact that the oral agents have made on the OTC markets is represented in Table 2 which was



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Representative Systemic Drugs Shifted from Rx to OTC Status*

Ingredient** (Shifted by:)	Dose (Adult)	Indication	Example Trade Name
Brompheniramine (Panel)	4 mg	antihistamine	Dimetane
Brompheniramine (NDA)	12 mg CR	antihistamine	Dimetane Extentabs
Chlorpheniramine (Panel)	4 mg	antihistamine	Chlor-Trimeton
Chlorpheniramine (NDA)	12 mg CR	antihistamine	Chlor-Trimeton Repetabs
Dexbrompheniramine (NDA)	6 mg CR	antihistamine	in Drixoral
Diphenhydramine (NDA)	25 mg	antitussive	Benylin
Diphenhydramine (Panel)	50 mg	sleep-aid	Sominex 2
Diphenhydramine (Panel)	25 mg	antihistamine	Benadryl-25
Doxylamine (NDA)	25 mg	sleep-aid	Unisom
Doxylamine (Panel)	12.5 mg	antihistamine	in Nyquil
Ibuprofen (NDA)	100 mg	analgesic	Advil, Nuprin
Loperamide (NDA)	2 mg	antidiarrheal	Imodium AD
Phenylpropanolamine (NDA)	75 mg CR	decongestant	in Triaminic 12
Pseudoephedrine (Panel)	60 mg	decongestant	Sudafed
Pseudoephedrine (NDA)	120 mg CR	decongestant	Sudafed 12-Hour
Pyrantel pamoate (Panel)	up to 1 gm	anthelmintic	Antiminth
Triprolidine (Panel)	2.5 mg	antihistamine	in Actifed
Triprolidine (NDA)	5 mg CR	antihistamine	in Actifed 12-hour

* Topical drugs will be included in Part III of this series.

** Panel = FDA Advisory Panel on OTC Drugs; NDA = Shift via New Drug Application Mechanism; CR = Controlled release dosage form.

derived from a report by the Nonprescription Drug Manufacturers Association. It lists the percentages of OTC products available in 1992 that contained switched drugs.

Current Status of Switches

Because the OTC review has taken longer than anticipated, some have charged that FDA has been "dragging its feet." The agency has responded that it performed as well as can be expected given its limited resources for nonprescription drug

review and the extensiveness of its task. FDA claims that 75 percent of the monographs will be completed by the end of 1993, 90 percent will be finished by the end of 1994, and the remainder will be done by the end of 1997. The pace depends on its ability to allocate staff.

The agency has completed 36 Final Monographs for 85 therapeutic categories, and it states the decisions on the most important or potentially unsafe products are completed. Overwhelmingly, the majority of commercial products affected by the review have already been reformulated or relabeled.

There has been a flurry of removal of OTC ingredients without proven safety and/or effectiveness over the past 12 to 18 months. In mid-1991, FDA announced it was banning 111 ingredient in OTC weight control products. During 1992, 415 ingredients previously claimed to be safe and effective for use as digestive aids, topical antifungal, external analgesics, pediculicides, skin protectants, menstrual and premenstrual products, and analgesics, antipyretics and antirheumatic drugs were banned from future sale.

In June 1993, FDA announced that there was a lack of evidence for making a claim of effectiveness for all previously available ingredients in OTC fever blister remedies and smoking deterrents, and that they must be removed from the market by December 1993.

Since the expert panels have been disbanded and the monograph development is over, FDA needs a mechanism to obtain advice on OTC products already marketed, and drugs potentially marketable over the counter. To accomplish this, the agency has initiated an Over-The-Counter Drugs Advisory Committee consisting of pharmacists, physicians, industry personnel and consumer representatives. The committee has been formed and is going through its organizational stage at the time of preparation of this lesson.

**Percentage of Current
OTC Products
Containing Ingredients
Switched from Rx to
OTC Status**

Category	Percentage
Menstrual	57%
Hay fever	49%
Premenstrual	48%
Diarrhea	41%
Muscle/Back Pain	35%
Upset Stomach	31%
Arthritis	30%
Common Cold	28%
Sinus problems	25%
Virus/flu	22%
Headache	19%

Table 2

As will be explained further in the next lesson in this series, the FDA review panels have been disbanded and drugs are currently switched from Rx-only to OTC status via the New Drug Application process.

Patient Counseling

Many significant pharmacologically active drugs have been switched from prescription to OTC status. Unfortunately, market experts who monitor OTC sales estimate that pharmacy (which once enjoyed 100 percent of the prescription sales of these products), has lost more than 60 percent of sales to non-pharmacy outlets since their switch to OTC status.

One potential means of reducing this loss with past and future switching is to let the public know that pharmacists are willing and able to counsel them on the proper selection and use of the medication they take.

It is obvious that a segment of society is convinced that all that matters in what they buy is price. However, another significant segment looks beyond that and, given the freedom to choose, will purchase their needs from pharmacists who present themselves as knowledgeable, are willing to help them, and recognize them as a unique fellow human being looking for service.

With this in mind, the following is offered as a guide to patient counseling on the drugs switched from Rx to OTC. Because of the

extensiveness of information, the drugs have been divided into systemic medications, which will be covered in this lesson, and topical products, the subject of the next lesson in this series. The monographs will be presented separately as self-standing reviews of important information to use in counseling individuals selecting each type of OTC product for self-medication.

General Information for OTCs

1. Read all of the labels on the package before using this product. If you have any questions regarding this medicine, ask your pharmacist or doctor.
2. Take only as directed. Do not take more doses or use more often than recommended on the product's label.
3. Any medicine can cause side effects, but most people experience few or none from their medicine. However, if the medicine is bothering you and causing unusual reactions, call your doctor or pharmacist.
4. Be sure to tell your pharmacist about allergies you have and any medicine before selecting over the counter products.
5. Call your doctor if you develop a skin rash, hives or itching, swelling of the face or difficulty in breathing while taking this medicine. These are signs of an allergic reaction.



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6. Do not take any medicine if you are pregnant, intend to become pregnant or are breast-feeding an infant without first checking with your doctor.
7. Store your medicine in a cool, dry place. Unless the product is individually wrapped, your bathroom "medicine cabinet" is not a good place to store it because of high humidity.
8. Do not use or keep outdated medicine. The expiration date should be printed on the package by the manufacturer.
9. Keep all medicine out of the reach of children.
10. In case of accidental overdose or ingestion by a child, call your doctor or poison control center immediately.

Counseling for OTC Antihistamines

1. This medicine is for temporary relief of runny nose, sneezing, itching of the nose or throat and watery eyes due to hay fever or other upper respiratory allergies.
2. The regular tablets and capsules can be taken with food or on an empty stomach.
3. The liquid dosage forms of this medicine should be measured accurately. Specially marked devices are available to assure you measure an accurate dose. If none is supplied with the product you select and you want one, ask your pharmacist.
4. The controlled release forms of this medicine should be swallowed whole. Do not chew or crush them.
5. Possible side effects from this medicine include drowsiness, dry mouth, dizziness or blurred vision.
6. This medicine may make you drowsy or dizzy. Do not drive a car, operate dangerous machinery or do jobs that require alertness until you know how you are going to react to it.
7. Do not drink alcoholic beverages if they increase drowsiness.
8. Do not take this medicine if you have glaucoma, asthma, other respiratory problems or difficulty in urination due to enlarged prostate without first checking with your doctor.
9. Do not give this medicine to children under 6 years of age, unless directed by a doctor.
10. Consult your doctor or pharmacist before taking other medicines containing an antihistamine.

Counseling for OTC Decongestants.

1. This medicine is used for temporary relief of nasal congestion or stuffiness from colds, sinusitis, hay fever or other upper respiratory allergies.
2. The regular tablets and capsules can be taken with food or on an empty stomach.
3. The liquid dosage forms of this medicine should be measured accurately. Specially marked devices are

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available to assure you measure an accurate dose. If none is supplied with the product you select and you want one, ask your pharmacist.

4. The controlled release forms of this medicine should be swallowed whole. Do not chew or crush them.
5. Possible side effects from this medicine include nervousness, dizziness, restlessness, and trouble sleeping.
6. Do not use this medicine if you have high blood pressure, diabetes, heart or thyroid disease, or difficulty in urination due to enlarged prostate without first checking with your doctor.
7. Do not take this medicine if you are taking a prescription drug for depression without checking with your doctor.
8. Do not take other decongestants without checking with your doctor or pharmacist.
9. Do not give liquid form of this medicine to children under 2 years of age, or the controlled release capsules or tablets to children under 6 years of age, unless directed by your doctor.
10. If symptoms do not improve in 7 days or a high fever occurs, contact your doctor.

Counseling for OTC Antitussive/Antihistamines

1. This medicine is used for the temporary relief of coughs due to minor throat and bronchial irritation as may occur with the common cold or with inhaled irritants.
2. The liquid dosage forms of this medicine should be measured accurately. Specially marked devices are available to assure you measure an accurate dose. If none is supplied with the product you selected and you want one, ask your pharmacist.
3. Possible side effects from this medicine include drowsiness, dry mouth, dizziness or blurred vision.
4. This medicine may make you drowsy or dizzy. Do not drive a car, operate dangerous machinery or do jobs that require alertness until you know how you are going to react to it.
5. Do not drink alcoholic beverages if they increase drowsiness.
6. Do not take this medicine for persistent or chronic cough such as occurs with asthma, emphysema, smoking, or when excessive phlegm is produced unless told to do so by your doctor.
7. Do not take this medicine if you have glaucoma, asthma, other respiratory problems or difficulty in urination due to enlarged prostate without first checking with your doctor.
8. Call your doctor if your cough lasts longer than 7 days, if it recurs, or if it is accompanied by a high fever, rash or persistent headache.
9. It may help clear chest congestion if you drink 8 to

10 glasses of water each day while taking this medicine.

10. Do not give this medicine to children under 6 years of age, unless directed by a doctor.
11. Consult your doctor or pharmacist before taking other medicines containing an antihistamine.

Counseling for OTC Ibuprofen

1. This medicine is used for the temporary relief of headaches, minor aches and pains, toothache, backache, minor pain of arthritis, menstrual cramps and reduction of fever.
2. Take the dose with a full glass of water.
3. If occasional and mild heartburn, upset stomach pain occur, you may take this medicine if you are allergic to aspirin or ibuprofen.
5. Possible side effects from this product include nausea, stomach pain, abdominal pain, mild heartburn and skin rash.
6. STOP taking this medicine and consult your doctor if you experience any unusual symptoms not present before you began taking it.
7. Do not take this medicine for more than 3 days for fever or 10 days for pain.
8. Do not give this medicine to children under 12 years of age, unless specifically directed by a doctor.
9. Consult your doctor or pharmacist before taking other medicines containing ibuprofen.

Counseling for OTC Sleep-aids

1. This medicine is used to help reduce difficulty in falling asleep.
2. This medicine should be taken 30 minutes before bedtime as directed on the product label.
3. Do not drive a car, operate machinery, or perform tasks that require alertness until you know how you will react to this medicine.
4. Do not drink alcoholic beverages in the evening while taking this medicine.
5. Do not give to children under 12 years of age.
6. If sleeplessness continues for more than 2 weeks, call your doctor.
7. Do not take this medicine if you have asthma, glaucoma, emphysema, chronic lung disease, shortness of breath, difficulty breathing, urinary tract obstruction or prostate gland enlargement, unless directed by your doctor.
8. Consult your doctor or pharmacist before taking other medicines containing an antihistamine.

Counseling for OTC Loperamide

1. This medicine is used to treat diarrhea.
2. For best results, take this medicine at the first sign

of diarrhea and after each subsequent bowel movement but no more often than 4 doses in any 24-hour period unless directed by your doctor.

3. The liquid dosage forms of this medicine should be measured accurately. Use the specially marked device that comes with the liquid to assure you measure an accurate dose. If none is supplied with the product you selected and you want one, ask your pharmacist.
4. Do not use this medicine if blood is present in your bowel movement.
5. Contact your doctor if nausea or signs of CNS depression such as dizziness or drowsiness occur.
6. Do not give this medicine to children under 3 years of age or use more than 2 days or in the presence of high fever unless directed by your doctor.
7. It is best to drink lots of fluids (8 or more glassfuls per day) when you have diarrhea to replace the water lost.
8. If you are taking antibiotics or have a history of liver disease, contact your doctor before using this medicine.

Adapted from the *Pharmex PALs* (Patient Advisory Leaflets). For more information, call (800) 233-0585.

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National Poison Prevention Week

Answers to Commonly Asked Consumer Questions

Poison Prevention Week Council



What is National Poison Prevention Week?

Public Law 87-319 authorizes the President to designate annually the third week in March as National Poison Prevention Week. This act of Congress was signed into law on September 26, 1961, by President Kennedy, after which the Poison Prevention Week Council was organized to coordinate this annual event. Congress intended this event as a means for local communities to raise awareness of the dangers of accidental poisonings and to take such preventive measures as the dangers warrant.

If my child is accidentally poisoned or eats or drinks a substance which might be poison, where can I find information on treatment?

If you think someone has been poisoned, call your poison control center immediately. There are currently some 100 Poison Control Centers in the United States which maintain information for the physician or the public on recommended treatment for the ingestion of household products and medicines. They are familiar with the toxicity (how poisonous it is) of most substances found in the home or know how to find this information. Their phone number can be found on the inside cover of the yellow or white pages of the telephone directory. Keep the number on your phone.

Are there some first aid measures I can take when an ingestion takes place?

Remain calm. Not all medicines and household chemicals are poisonous, and not all exposures necessarily result in poisoning. For medicines, call the Poison Control Center or physician immediately. For household chemical products, follow first aid instructions on the label, then call the Poison Control Center or physician. If unable to contact them, call your local emergency number (911 in most areas) or the operator. Keep the number on your phone.

Have the label ready when you call the expert. The label provides information concerning the product's contents and advice on what immediate first aid to perform. This will be useful when giving first aid and when you call the Poison Control Center.

The expert will need to know:

- The victim's age
- The victim's weight.
- Existing health conditions or problems.
- The substance involved.
- Was it swallowed, inhaled, absorbed through skin contact, or splashed into the eyes.
- Any first aid which may have been given.
- If the person has vomited.
- Your location, and how long it will take you to get to the hospital.

If medicine has been swallowed, do not give anything by mouth until advised by the Poison Control Center.

If chemicals or household products

have been swallowed, offer a small amount of water. Then call for professional advice about whether or not you should make the patient vomit.

Always keep on hand at home a one-ounce bottle of syrup of ipecac for each child or grandchild under age 5 in the home. Use only on advice of the Poison Control Center, emergency department, or physician.

Why do so many accidental poisonings happen to children under five years of age?

Children under the age of five are in stages of growth and development in which they are constantly exploring and investigating the world around them. This is the way they learn. It is a normal characteristic and should not be discouraged. Unfortunately, what children see and reach for they usually put in their mouths. It is this hazard to which parents must be alerted. As the youngsters' mobility, ingenuity, and capabilities increase, they can reach medicines and household chemicals even if stored up high. For instance, when children are crawling, they can find such products as drain cleaners stored under the kitchen sink and on the floor. As soon as they are able to stand, they can reach such products as furniture polish on low-lying tables, as well as medications in purses on beds. When they start to climb, they can reach medicine on counter tops or open the medicine cabinet and get to the medicine. These products should be locked up where possible, out of the child's reach-- even when safety

packaging is used. Adults should never leave a medicine or household chemical product unattended while in use; children act fast and can get hold of a product and swallow it during the short time while the adult is answering the doorbell.

If I find my youngster playing with a bottle of medicine or some household product, how can I tell if he or she has swallowed some and what should I do?

Reactions vary, depending on the product. Sometimes the child may vomit; or he or she may appear to be drowsy or sluggish. Some of the substances may remain around the child's mouth and teeth. There may be burns around the lips or mouth from corrosive items; or you may be able to smell the product on the child's breath. If a household chemical has been ingested, follow the first aid instructions on the label and then get medical advice -- even if you suspect, but don't know for sure, that your child has ingested a potentially hazardous product. Call your Poison Control Center, emergency department, or physician. Place these telephone numbers on your phone.

Why do we need child-resistant packaging?

Although labeling requirements and educational programs have had some effect in reducing the numbers of childhood ingestion, significant numbers of children are still being poisoned by accidentally ingesting household products, and solvents.

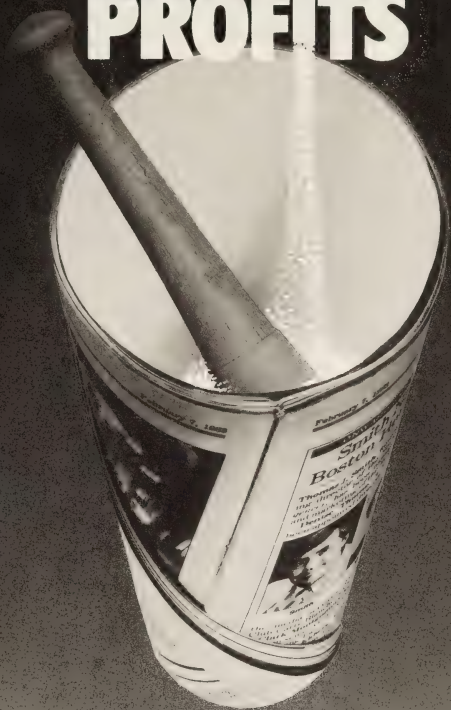
Child-resistant packaging, if used properly, provides an additional barrier to help prevent accidental ingestion.

As a parent, how certain can I be regarding the effectiveness of this kind of packaging?

While child-resistant packaging provides an increased element of protection, children are going to investigate several different ways of opening a container. If their fingers won't work, their teeth might. It would be impossible to manufacture a package or a closure that would prevent every single child from getting into the contents under all possible circumstances. Therefore, the Poison Prevention Packaging Act requires that packages be difficult for children under five years of age to open and obtain a toxic amount within a reasonable time. For example, U.S. Consumer Product Safety Commission regulations require that aspirin, and other products, be packaged in special containers which would prevent at least 80% of those children tested from opening the container during a 10-minute test. This requirement means that some children would still be able to open or otherwise obtain a toxic amount. So, keep poisonous substances locked up.

Continued on page 19.....

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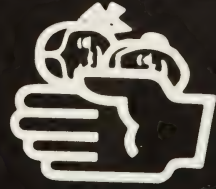
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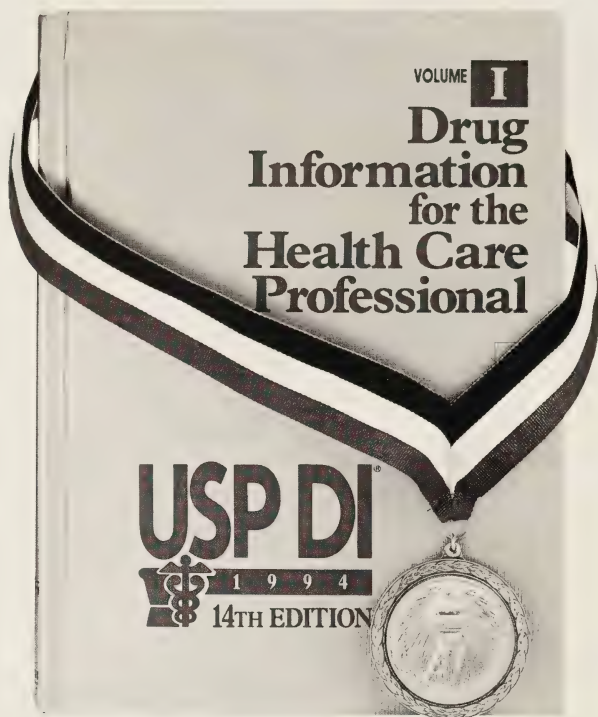


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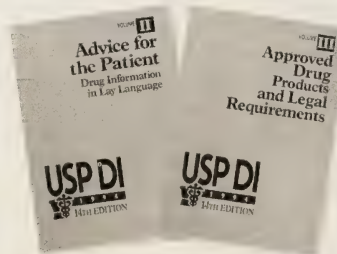
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How can I use child-resistant packaging properly?

Remember these steps: (1) Read instructions to make it easier to open the packaging. (2) Be sure to reseal the closure tightly. Never transfer the contents to other containers. (3) Do not leave loose pills on the table or kitchen counter. (4) Keep medicines and household products (even those with safety caps) out of sight. Use locks or child-resistant latches to secure storage areas. The pharmacist from whom the product was purchased can teach you how to open and close the packaging, if you have difficulty. Opening and closing becomes easier with practice. While it may take a few additional seconds of your time, those few seconds may save the life of a child who is very dear to you.

What kind of products can I expect to find in child-resistant packaging?

Aspirin and aspirin-substitutes (acetaminophen), certain types of liquid furniture polish, oil of wintergreen, drain cleaners, oven cleaners, lighter fluids, turpentine, paint solvents, windshield washer solution, automobile antifreeze, pesticides, oral dosage prescription drugs, iron-containing drugs and dietary supplements, over-the-counter ibuprofen, and loperamide (an anti-diarrhea medicine) are among the substances required to be in child-resistant packaging. The CPSC proposed child-resistant packaging for over-the-counter preparations containing lidocaine and dibucaine (anesthetic medicines) and is considering a petition that requests child-resistant packaging for mouthwash containing more than five percent alcohol.

There are no small children in my home. Do I have to use child-resistant packaging?

In general, all adults should use child-resistant packaging because young children may visit the adult's home. To benefit people who are elderly or handicapped, the Poison

Prevention Packaging Act allows a manufacturer to offer a regulated non-prescription product in one size or package that doesn't comply with the safety packaging standard and that bears the label statement "This package for households without young children," if that manufacturer also offers the same product in child-resistant packages.

Deaths Due to Medicines and Household Chemicals

Year	# Deaths
1972	216
1973	149
1974	135
1975	114
1976	105
1977	94
1978	81
1979	78
1980	73
1981	55
1982	67
1983	55
1984	64
1985	56
1986	59
1987	31
1988	42
1989	55
1990	49

This represents a decline of 77% since 1972.

Source: National Center for Health Statistics

Additionally, if a prescription is involved, the purchaser or prescribing physician can request regular, non-child-resistant packaging. However, such requests should be kept to a minimum, since they increase the danger of childhood poisonings. Accidents have happened when older persons carried medicines into homes that have small children. A study conducted for the U.S. Consumer Product Safety Commission by the American Association of Poison

Control Centers found that 23% of the oral prescription drugs that were ingested by children under 5 belonged to someone who did not live with the child. Overall, 17% of the drugs ingested belonged to a grandparent or great-grandparent. This percentage varied from city to city: in Salt Lake City, 9% of the drugs ingested belonged to a grandparent, but in Shreveport, Louisiana, 24% of the drugs ingested belonged to a grandparent. The data suggested that grandparents -- and all adults -- need to use child-resistant packaging and keep medicines properly secured, away from young children.

Is there any evidence that the number of child poisonings has decreased since child-resistant packaging began to be used?

Yes. The staff of the U.S. Consumer Product Safety Commission (CPSC) estimates that child-resistant packaging for aspirin and oral prescription medicine saved the lives of about 700 children since the requirements went into effect in the early 1970's.

CPSC analyzed child fatality data for accidental ingestion of aspirin and oral prescription medicines. The death rates for aspirin and oral prescription medicines declined even after taking account of the overall decline in the accidental child death rate from all causes. The study also accounted for changes in per capita product consumption and reductions in the aspirin fatality rate associated with therapeutic overdose.

The CPSC study showed that child-resistant packaging reduced the aspirin-related child death rate by up to 0.88 deaths per million children under age five. The results also showed that special packaging reduced the oral prescription medicine-related death rate by up to 1.27 deaths per million children under age five. This represents a fatality rate reduction of up to 45 percent from levels that would have been projected in the absence of child-

resistant packaging requirements.

The estimate of about 700 lives saved relates to aspirin and oral prescription medicines only and does not include additional lives that may have been saved by child-resistant packaging on other products.

There has been a reduction in deaths with all household chemicals and with aspirin products in particular since 1972 (when aspirin was first required to be in child-resistant packaging).

Deaths Due to Aspirin Products

Year	# Deaths
1972	46
1973	26
1974	24
1975	17
1976	25
1977	11
1978	13
1979	8
1980	12
1981	6
1982	5
1983	7
1984	7
1985	0
1986	2
1987	3
1988	3
1989	2
1990	1

This represents a decline of 98% since 1972.

Source: National Center for Health Statistics

However, the number of ingestion or exposures to household medicines and chemicals continues to be high. The American Association of Poison Control Centers reports that in 1992 the number of children under the age of 5 exposed to potentially poisonous substances was 1,095,358. According to the AAPC National Data

Collection System, in 1992 there were 29 deaths to children under age 5 who accidentally swallowed medicines and household chemicals.

Are there any good housekeeping rules I can use to prevent poisoning accidents?

Keep all household chemical products and medicines (especially iron pills and food supplements containing iron) out of sight of youngsters and, preferably, locked up when not in use. Medicines and household chemicals on kitchen counters or bathroom surfaces are very accessible to young children.

When these products are in use, *never let them out of your sight* -- even if you must take them along when answering the telephone or the doorbell.

Store all medicines separately from household products, and store all household chemical products away from food.

Keep items in their original containers.

Leave the original labels on all products, and read the label before using.

Always leave the light on when giving or taking medicines.

Review the medicine cabinet periodically, and safely dispose of unneeded medicines when the illness for which they were prescribed is over. Pour contents down drain or toilet, and rinse containers before discarding.

Can miniature "button" batteries present a risk of childhood poisoning?

Yes, miniature batteries may cause poisoning if accidentally swallowed. The batteries can cause internal burns if they become lodged in the esophagus or intestinal tract. These tiny batteries (used in watches, calculators, cameras, and hearing aids) usually pass through the person without any problem. However, if a miniature battery is swallowed, you should contact your poison center, your physician, or the National

Button Battery Ingestion hotline at (202) 625-3333. In order to prevent ingestion of miniature batteries, consumers should keep the batteries out of children's reach and throw away old batteries, securely wrapped, after they have been removed from the appliance.

What can consumers do to protect themselves and their families from tampering with medicines?

Although most medicines are packaged in tamper-evident packaging, they are not tamper-proof. Each consumer must be alert for the packaging to be protective. Here's how you can help protect yourself and your family:

- Read the label. Over-the-counter medicines with safety closures tell you on the label what tamper-evident features you should look for on the package.
- Inspect the outer packaging. Look before you buy!
- Inspect the product itself when you open the package. Look from others in the package.
- Look for tablets or capsules that are different in any way from others in the package.
- Don't use any medicine from a package that shows cuts, slices, tears, or other imperfections.
- Never take medicine in the dark.
- Read the label and look at the medicine every time you take a dose
- Whenever you suspect something wrong with a medicine or its packaging, take it to the store manager.
- Tamper-evident packaging can help protect you if you are alert!


What can consumers do to protect children from pesticide-related poisonings?

A recent survey by the U.S. Environmental Protection Agency regarding pesticide use in and around the home revealed that almost half (47%) of all households with children under the age of five had at least one pesticide stored in an unlocked

cabinet, and less than 4 feet off the ground (i.e., within reach of children). The survey also found that 75% of households without children under the age of five also stored at least one pesticide within reach of children. This number is especially significant because 13% of all pesticide poisonings occur in homes other than the child's home. Adults should take the following steps to safeguard children from accidental exposures to pesticides:

- Always store pesticides away from children's reach, in a locked cabinet or garden shed.
- Read the label first and follow the directions to the letter, including all precautions and restrictions.
- Before applying pesticides (indoors and outdoors), remove children and their toys from the area and keep them away until it is dry or as recommended by the label.
- Never leave pesticides unattended when you are using them -- not even for a few minutes.
- Never transfer pesticides to other containers -- children may associate certain containers with food or drink.
- Use child-resistant packaging properly by closing the container tightly after use.
- Alert others to the potential hazard, especially grandparents and care givers.

Where can I get more information on preventing poisonings?

See the "List of Materials -- 1994" for available resources and their sources of supply. The list can be obtained from Secretary, Poison Prevention Week Council, P.O. Box 1543, Washington, DC 20013. 

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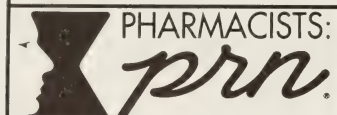
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March 1994 -- OTC Switches II

This month's questions are taken from the article on OTC Drug Switches which begins on page four. Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by August 31, 1994. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

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1. All of the following is appropriate information to counsel patients when selecting loperamide except:

- a. Do not give this product to children under 3 years of age unless directed by your doctor.
- b. If the diarrhea has not cleared up after 7 days' use, contact your doctor.
- c. Drink lots of fluids when you have diarrhea.
- d. Tell your doctor if nausea, dizziness or drowsiness occur.

2. Prior to 1972, prescription drugs were switched to OTC status:

- a. by regulation on request from manufacturers or other interested persons
- b. by the FDA's OTC drug product ingredient review mechanism
- c. by the New Drug Application mechanism
- d. on petition by the Over-The-Counter Drug Advisory Committee

3. All of the following drugs were switched from Rx-only to OTC status prior to 1972 using the mechanism referred to in question #2 except:

- a. acetaminophen
- b. dextromethorphan
- c. ibuprofen
- d. tolinaftate

4. The largest group of products switched from Rx-only to OTC status is used to treat:

- a. arthritis
- b. diarrhea
- c. menstrual problems
- d. sinus problems

5. The advice "Do not give the liquid form of this medicine to children under 2 years of age," and, "if symptoms do not improve in 7 days or a high fever occurs, contact your doctor," is most appropriate for which of the following groups of drugs?

- a. Ibuprofen
- b. Antihistamines
- c. Antitussive/Antihistamines
- d. Oral decongestants

6. In mid-1991, FDA announced its intention to ban the OTC marketing of 111 ingredients in which of the following classes of drugs?

- a. Nasal decongestants
- b. Ophthalmic vasoconstrictors
- c. Psoriasis remedies
- d. Weight control products

7. Patients selecting an OTC antihistamine should be advised to check with their doctor first if they have which of the following diseases?

- a. Diabetes
- b. Glaucoma
- c. Heart disease
- d. High blood pressure

8. The advice referred to in question #7 is appropriate for all of the following except:

- a. antidiarrheals (e.g., loperamide)
- b. antitussives (e.g., Benylin)
- c. hay fever remedies (e.g., Dimetane)
- d. sleep aids (e.g., Sominex-2)

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Pharmaceutical Care

Stanley M. Shepperson, Pharmacy Student, UMAB School of Pharmacy

This article is the third in a series written by pharmacy students in the first course of the new entry-level Pharm.D. program at the University of Maryland School of Pharmacy. PHAR 516 (Pharmacy Practice and Education) is an introductory course which exposes the students to pharmacy practice, pharmaceutical sciences, ethics, communication, and critical thinking. One of the class assignments was to write a critical evaluation on one of three topics: pharmaceutical care, pharmacy technicians, or mail-order pharmacy. This course was developed by MPhA Past President Ilene Zuckerman with the assistance of MPhA member and graduate student Diane McNalley.

Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.¹ An effective pharmaceutical care environment encompasses a variety of conditions that must be met by practitioners and patients.

In preparing for the forthcoming demand of pharmaceutical care, pharmacists must overcome barriers that impede upon their abilities to provide effective drug therapy and patient safety. Likewise, patients must also demonstrate efforts aimed at learning more about the services and provisions that pharmacist are capable of delivering. Some of the goals accomplished under an effective pharmaceutical care regimen include reduced patient non-compliance, overdosage, and other types of drug misuse.

With the emergence of the present pharmaceutical care issue has come a variety of reactions by pharmacists and patients. Though many pharmacists have recognized the importance of pharmaceutical care, many are not certain about how to implement these practices. These hindrances stem from deficiencies in both practitioners and patients. However, none of these factors are solely responsible for pharmaceutical care inefficiency.

Logistical barriers are significantly responsible for lack of communication between patients and pharmacists. A pharmacy that is aimed at providing pharmaceutical care should make efforts to remove physical barriers that separate practitioners and patients. Pharmaceutical care is impossible if patients cannot gain

access to pharmacists. Some Arkansas pharmacists, in realization of this obstacle, have developed a regulation stating that pharmacists should counsel patients "face-to-face" if the patient is in the pharmacy.²

Some pharmacists are not communicating with patients for other reasons, including lack of effective communication skills. Pharmacists may often be uncertain about how or what to tell patients about medications. Though pharmacists are competent and qualified to practice pharmacy, their interactions with patients may not signal them to question their abilities to interact with patients. When problem situations do arise, a pharmacist may easily place the blame on patient "attitudes".³

Many patients, however, are not aware of the attempts of pharmacist to provide them with necessary facts and instructions. For example, in a study published by *The American Druggist*, one patient stated that she perceived pharmacists as order-fillers and would never consult them for advice because they always seemed too busy. The patient in this case suggested that pharmacists post signs reading, "Feel free to ask us questions".⁴ These examples demonstrate that patients harbor a variety of assumptions about pharmacists' abilities and intentions in providing pharmaceutical care. In alleviating these types of barriers to communication, pharmacists need to become enrolled in health education programs and communication workshops so that any deficiencies can be assessed.

Poor communication skills cannot always, however, be blamed as the cause of pharmacists' lack of

willingness to provide critical drug information. A main reason why pharmacists may withhold drug information is because of fear of "scaring" patients into not taking medications. Using such rationale seems somewhat irresponsible since some side effects could have serious implications.⁵

Some pharmacists may be unwilling to provide extensive pharmaceutical care due to lack of reimbursement for their added efforts. Pharmacies may have to sacrifice valuable time in providing pharmaceutical care. Besides time factors, there is little reason for pharmacists to refuse to provide pharmaceutical care for patients. In abiding by the code of ethics for pharmacists, these practitioners should be enthusiastic about informing patients of the functions and potential problems associated with medications.

Since reimbursement for pharmacists would certainly be more costly to the patient and some pharmacists feel a need to be compensated for their services, a third party may become involved in meeting the needs of both. A study featured in *The American Journal of Hospital Pharmacy* demonstrates instances where lengths of hospital stays were reduced for patients who received effective drug information and followed specific usage instructions.

A possible strategy would be to influence third party insurers to provide pharmacists with the financial incentives to provide pharmaceutical care. Insurers pay for extended hospital stays and visits to physicians that have resulted from preventable drug-related occurrences, therefore making them the most ideal candidates.⁶

Realizing that insurance companies may become overwhelmed by claims concerning pharmaceutical care, an ideal pharmacy should provide the third party payer with a certificate of need prepared by a physician, a description of the pharmaceutical care services provided, and a separate

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billing statement for the services obtained. Such measures are necessary in helping the third party distinguish between dispensing activities and those that are more personal between pharmacists and patients. However, before any of these strategies can be implemented, pharmacists need to reach a consensus about what services require compensation and how they are to be administered.⁷ If not, potential third party payers will not find credibility in these projects.

Extensive counseling is undoubtedly impossible under certain circumstances, but some pharmacists may compensate for their limited time resources by providing patient

information leaflets as sources of drug and side-effect information. According to a particular patient education and compliance study, patients who received patient information leaflets were better informed about their medications and side-effect, and showed higher levels of treatment satisfaction than patients not receiving leaflets. Pharmacists, therefore need to have effective writing skills in providing understandable and appropriate literature for patients.⁸

Though deficiencies of pharmacists contribute, lack of pharmaceutical care implementation cannot become the responsibility of the pharmacist alone. Many patients strongly admit

that counseling by pharmacists should not be a service requiring the payment of fees, especially when it has been given over-the-counter for years at no charge. A reason for this attitude taken by patients results from a lack of understanding about what a consultation with a pharmacist would accomplish.⁹ Cooperation by both practitioners, patients, and third party payers may help solve some of the problems associated with the implementation of pharmaceutical care. These groups need to rationalize and debate certain issues, however, before any measures can be taken. **R**

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Expanding Liability

Continued from Page 28....

drug for IV administration. The pharmacy did not call the prescriber and did not call the error to the attention of the nursing staff. A nurse administered an IM injection, according to the physician's order. The patient suffered pain, swelling and a disability as a result of a mass in the area of the injection. The patient sued the hospital and physician, and the hospital sued to bring into the lawsuit the independent contractor who provided pharmacy services to the hospital.

In reviewing the case, the court referred to numerous previous cases, many of which have been digested in this column. As the court saw it, one line of cases absolved the pharmacist from responsibility for providing warnings to patients, while another line of cases implicated the pharmacist as being responsible for failing to correct an error in prescribing. The court referred approvingly to language from a previous case in which it was said, "The pharmacist has a duty to be alert for clear errors or mistakes in the prescription. The pharmacist does not, however, have a duty to question a judgement made by the physician as to the propriety of a prescription or to warn customers of the hazardous side effects associated with a drug, either orally or by way of the manufacturer's package insert."

The court held that a pharmacist has a limited duty to inquire or verify from the prescribing physician clear errors or mistakes in the prescription. In reply to the citation by the pharmacy of cases purporting to hold that it is the physician's responsibility to prescribe correctly, not the pharmacist's responsibility to assure accuracy in prescribing, the court stated, "We find the cases relied upon by Allied to be distinguishable from the instant case and concluded that the pharmacist had an affirmative duty in this case." The case will now proceed with the pharmacy included

as a defendant. The issue of whether a duty exists has been answered in the affirmative. Attention now will turn to whether that duty was breached.

Cases like this one involving Vibramycin, and the cases referred to in the *Wall Street Journal* make it clear that the pharmacist's legal responsibility is expanding. Pharmacists must detect and correct prescribing errors. Under state laws inspired by OBRA 90, pharmacists are required to do even more than that. One can only hope that additional expectations will bring additional rewards. **R**

About the Author

David Brushwood is Professor of Pharmacy Health Care Administration at the University of Florida. His articles on cases affecting pharmacies and pharmacy are provided as a courtesy to state pharmacist associations. Questions on legal issues affecting Maryland practice should be directed to your legal representative or the Maryland State Board of Pharmacy.

Expanding Liability

Is the Wall Street Journal Right?

David B. Brushwood, R.Ph., J.D.



Increasing pharmacist malpractice liability was big-time national news on October 29, 1993, when the *Wall Street Journal* ran a front page (second section) story titled "Suits Against Pharmacists Are on the Rise." The article described recent court rulings that have held pharmacists liable for harm to patients despite the fact that the pharmacists filled prescription orders accurately. As the article points out, as recently as a decade ago it would have been unheard of for a pharmacist to be held liable when the pharmacist had accurately processed a prescription order. Technical accuracy was what the law expected, and pharmacists did a good job of meeting that expectation.

Times are changing, however, and the article described two cases that are generally recognized as precedent setters. In one case, the patient was given a prescription for Cafegot Suppositories with directions to insert one every four hours for headache. Neither the physician nor the pharmacist instructed the patient to limit her use of the medication to two suppositories per headache and five suppositories per week. The patient overused the suppositories (one every four hours for three to four days), and suffered ergotamine poisoning. The patient sued both the physician and the pharmacist, and ended up collecting from both. The pharmacist had argued that the physician alone has responsibility for proper drug use, but the court disagreed. Worthy of note is that in such cases the physician is virtually always implicated along with the pharmacist. The question is usually whether the pharmacist should be held liable along with the physician is virtually always implicated along with the pharmacist, not whether the pharmacist should be held liable instead of the physician.

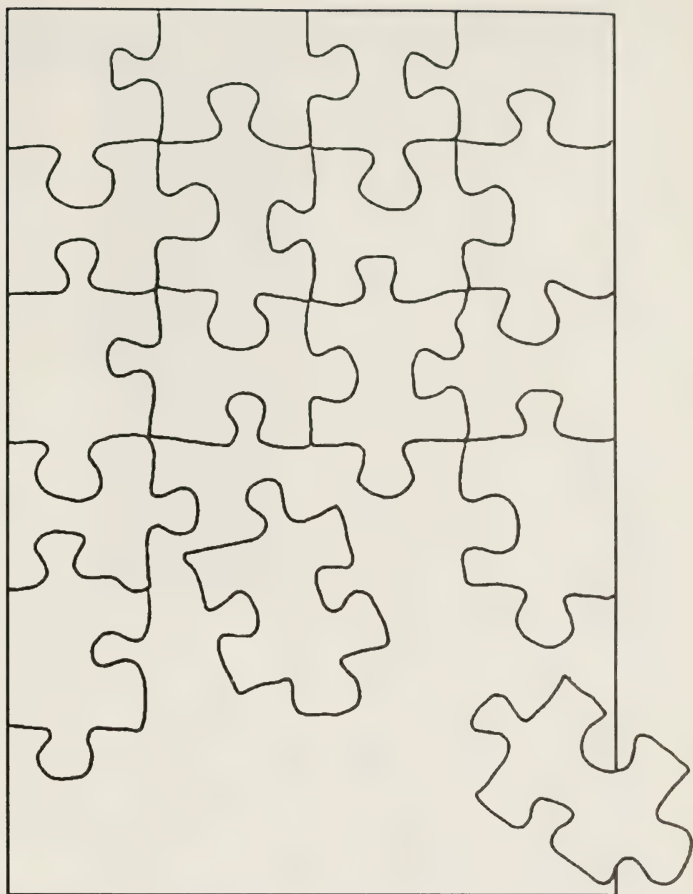
In the second case cited in the article, a child was allegedly dispensed theophylline and erythromycin at the same time. The interaction between the drugs resulted in seizures and permanent harm to the child. The physician and pharmacist were both sued, and the pharmacist asserted the commonly tried (and increasing less successful) defense that only the physician has responsibility for proper prescribing. The court disagreed, ruling that the pharmacist had a responsibility to detect and act on drug interactions.

The *Wall Street Journal* article quoted a representative of a major pharmacist malpractice insurance company as saying that between 1987 and 1990, claims against pharmacists rose by 22 percent. Not only that, the representative indicated that three times since 1991 it had paid \$41 million on a pharmacist liability claim, a damage threshold it had not reached once in the two previous decades.

A recent court case out of Louisiana lends credence to the *Wall Street Journal* story. The case of *Gassen v. East Jefferson General Hospital*, 1993 La. App. Lexis 3985 (Dec. 15, 1993) arose out of an order for medication in a hospital. The physician allegedly ordered Vibramycin 100 mg. IM two times daily. Since Vibramycin does not exist as an IM injection, the hospital pharmacy corrected the order, filled it with IV Vibramycin, and labeled the

Concluded on Page 27....

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The Maryland Pharmacist

VOL. 70

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NO. 4



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The Maryland Pharmacist

The Official Journal of the Maryland Pharmacists Association

650 West Lombard Street, Baltimore, Maryland 21201-1572

April 1994

Volume 70

Number 4

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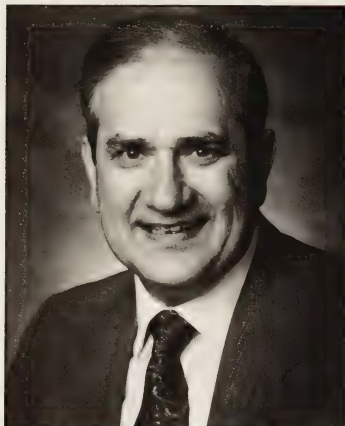
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President's Commentary

Howard Schiff, P.D.



A riddle: what do you get if you promise not to do something tomorrow that you didn't do yesterday, and which you might be allowed to do two days from now? Well, if you're dealing with the Federal Trade Commission, you get a consent order.

As I reported to you in the November 1993 issue of *The Maryland Pharmacist*, the Federal Trade Commission issued a complaint against the Baltimore Metropolitan Pharmaceutical Association and the Maryland Pharmacists Association. This complaint was the result of five years of investigation, document review, and depositions. The complaint centered around alleged anti-trust violations by the two organizations in their dealings with the City of Baltimore's employee prescription program and Prudential Insurance Company.

This past month, a consent order negotiated by BMPA and MPhA was formally accepted by the Federal Trade Commission. A consent order essentially is a promise by the two organizations to not violate any anti-trust laws -- in other words, we're agreeing not to break the law.

The confusing part of this whole issue is that we didn't break any anti-trust laws in the past! In order for the Federal Trade Commission to prove that laws were violated, they would have had to take us to court. Allegations of anti-trust violations are hard to prove with a preponderance of facts. There is a lot of "gray" surrounding alleged boycotts, collusion, etc. Therefore, it would be a long, drawn-out, expensive court case for BMPA and MPhA to fight.

Why didn't we fight the FTC if we knew we were innocent? Frankly, it's because the Board of Trustees of MPhA and the Executive Committee of BMPA just didn't think that spending thousands upon thousands of dollars in court costs was in the best interests of our members.

Under the final consent order, MPhA and BMPA are "prohibited from entering into, organizing or encouraging any agreement between or among pharmacy firms to refuse to enter into, or to withdraw from, any participation agreement offered by a third party." We don't do that anyway... never did.

We cannot provide "comment or advice to any pharmacist or pharmacy firm on the desirability or appropriateness of participating in any participation agreement." We don't do that either. We are allowed to give the facts about a third-party program... that, we do and will continue to do to keep you informed.

The consent order does carry the force of the law and we can be fined up to \$10,000 for each violation. And boy, that's definitely something we don't want to do!

This issue of *The Maryland Pharmacist* contains a copy of the FTC's complaint against us, the final consent order, and an analysis of both. Please read each one thoroughly as they can affect you as a member of this organization. Also, for all MPhA members, take advantage of the free one hour of continuing education in this issue only to test your familiarity with this situation.

R

Questions and Answers About the Consent Order

Between the FTC, BMPA and the Maryland Pharmacists Association

David G. Miller, P.D., Executive Director, Maryland Pharmacists Association



These questions and answers have been prepared to explain the consent order to which the Baltimore Metropolitan Pharmacists Association, the Maryland Pharmacists Association and the Federal Trade Commission have jointly agreed.

MPhA's attorney Joseph S. Kaufman and MPhA's officers, trustees and staff engaged in extensive negotiations with the Federal Trade Commission representatives regarding both the concepts and the crafting of the words used in the consent order. As a result of those negotiations, and with the approval of the Board of Trustees of the Maryland Pharmacists Association (MPhA) and the Executive Committee of the Baltimore Metropolitan Pharmacists Association (BMPA), a revised version of the original proposed consent order was prepared and submitted to the Federal Trade Commission (FTC). The final consent order was approved by both governing groups of the two organizations in late 1993. The Federal Trade Commission, after a required 60 day public comment period, accepted the final version of the consent order on March 1, 1994.

What was the origin of the dispute?

For years, the City of Baltimore contracted with Blue Cross/Blue Shield of Maryland to underwrite and administer its employees' prescription drug program. In 1987, Blue Cross lost that insurance contract to Prudential Insurance Company in an open-bidding process. Prudential then sub-contracted with PCS to administer the program. Plan 354

was the plan number assigned by PCS to the Baltimore City employees' prescription drug program. A reimbursement formula was part of the program.

In mid-August of 1988, Prudential Insurance Company sent a letter to all of its PCS-contracting pharmacy providers stating that effective August 15, 1988, Prudential was unilaterally reducing its reimbursement rate for Plan 354, administered by PCS, from AWP to AWP-10%.

The Baltimore Metropolitan Pharmacists Association immediately took action. Greg Wood, then executive director, contacted the Mayor, the President of the City Council, and other members of the City government to express outrage at the reduction and the short notice. Representatives of BMPA appeared before the Baltimore City Board of Estimates in late August 1988 to voice their complaints as well.

The City's response was sympathetic to the pharmacy community; they, too, were surprised by Prudential's unilateral action. However, the City had failed to stipulate in their contract with Prudential that changes in reimbursement had to be communicated and/or approved by the City before they were implemented.

BMPA then encouraged its members to write letters to Prudential, PCS, and their City representatives complaining of the reduction and informing them of whether or not they would continue as participating providers for Plan 354. Members

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were also asked to send copies of the letters to the BMDA offices at 650 West Lombard Street in Baltimore; these copies were for BMDA to use in showing the City officials the scope and significance of the problem. BMDA also informed its members that a clause in the Prudential contract with the City required that 100 pharmacies be participants at all times -- otherwise, the contract would be invalidated. The City asked BMDA to determine how many of the pharmacies would stop accepting the employees' PCS plan because of the lowered reimbursement.

Discussions between the City and Prudential and BMDA dragged on through the fall of 1988. At the end of October 1988, BMDA held a press conference to tell the media about the problems pharmacists were facing in obtaining fair and adequate reimbursement from Prudential. Additionally, BMDA announced that they believed that Prudential was in viola-

tion of their contract because enough pharmacies had decided to quit the program than was required to make the contract invalid.

Shortly thereafter, the City succeeded in having Prudential reinstate the reimbursement rate to the pharmacies for the remainder of the two-year contract. Prudential chose not to rebid when the contract came up for renewal in June of 1989 and Blue Cross again became the insurer and administrator until again losing the contract to Express Scripts in December 1992.

In July 1990, subpoenas were issued by the Federal Trade Commission for the Baltimore Metropolitan Pharmacists Association, the Maryland Pharmacists Association, and several pharmacies and pharmacists. These subpoenas requested any and all documents related to the 1988 Prudential/City contract dispute.

After turning over voluminous documentation, participating in

depositions, negotiating, meeting, negotiating some more, and finally coming to mutual agreement, BMDA, MPhA and the Federal Trade Commission signed a consent order and complaint.

Why are BMDA and MPhA both involved?

Although the activities surrounding the Baltimore City employees' prescription drug program, Prudential and PCS were undertaken solely by the Baltimore Metropolitan Pharmacists Association (BMDA), the Federal Trade Commission extended the scope of its investigation to the Maryland Pharmacists Association as well. This was because BMDA and MPhA have common offices and, at that time, BMDA contracted with the MPhA Executive Director as their Executive Director. In other words, the FTC perceived that for all intents and purposes the two organizations were acting together. While MPhA's



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attorney and leadership argued that the MPhA Association was not involved and that all documentation indicated that this was a BMPA activity, we were unable to convince the FTC staff of this fact.

Is the consent order like a plea bargain?

Absolutely not. The consent order specifically states that it "does not constitute an admission by respondents [BMPA and MPhA] that the law has been violated...." The consent order does not involve any concessions or agreements by MPhA or BMPA about the *facts* that occurred in the fall of 1988 nor does it involve any concessions or agreements that either organization was involved in any illegal activity. No guilt of any kind has been admitted; therefore, the consent order is quite different from a plea bargain, in which guilt is admitted in exchange for a lesser penalty or criminal charge.

Why should there be any settlement at all if nothing illegal happened?

The consent order reflects a compromise between MPhA, BMPA and the FTC. Since both pharmacist organizations denied any wrongdoing, the FTC would have had to conduct an administrative hearing (like a trial) in order to attempt to prove that laws were violated. Such a trial would have been quite expensive for both the BMPA, MPhA and even the FTC -- regardless of who won.

MPhA's leaders recognized that incurring excessive legal fees and was simply not in the best interest of you, our member. Considering that the alleged violation occurred more than five years ago, neither MPhA nor BMPA felt that dragging through the courts for several more years would have been a wise investment of the organizations' fiscal or staff resources. A consent order was the wisest, and least expensive, way to resolve this problem.

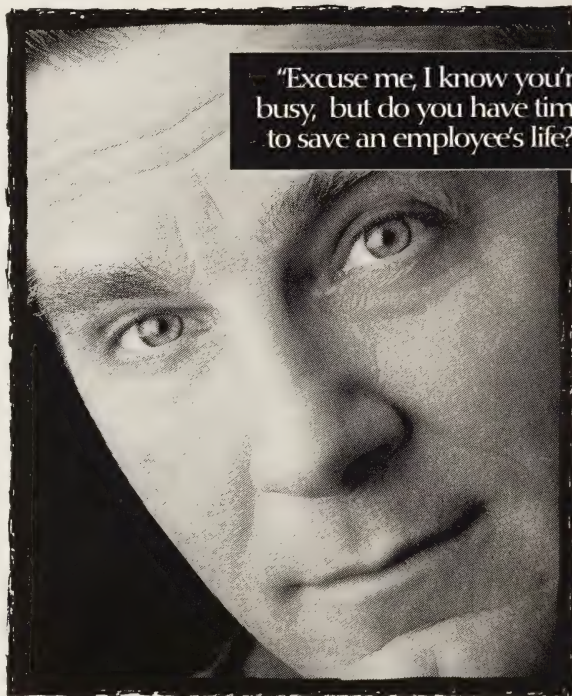
Why does the consent order address future activities of MPhA and BMPA?

Since we could not agree with the FTC that any violations had occurred *in the past*, the case was settled by focusing and agreeing instead on what will not occur *in the future*. Therefore, the consent order addresses only matters related to our activities in the future. As the Board of Trustees would explain it, "we've agreed not to do from now on what we didn't do before." It is quite

confusing but is typical and normal in consent orders issued by the FTC.

What does the consent order require of pharmacists?

Essentially, the consent order can be divided into two general categories. The first category addresses future activities of BMPA and MPhA, and by extension, their members. The second category is informational actions that the organizations must undertake to inform their members and to guarantee compliance with the first category.



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What are the future BMDA and MPA activities addressed in the consent order?

The consent order contains four items related to MPA and BMDA. All four items are matters related to activities which are prohibited under the antitrust laws and which MPA and BMDA agree that they will not do. The consent order is effective for five years -- from March 1, 1994 to March 1, 1999.

Since the activities are prohibited by the antitrust laws in any event, our agreement not to do any of these acts is not a significant concession. In other words, no association can legally do any of the acts specified below, regardless of whether there has been any FTC investigation or consent order. Therefore, we are not conceding any legal or practical flexibility because all four of the activities specified below are already things we could not do.

The four future activities addressed in the consent order are as follows:

1. Neither MPA nor BMDA shall direct its members, either through direct or implied instructions, to join, refuse to join, or withdraw from any third-party prescription drug program. Individual pharmacies and pharmacists must, as always, make their own independent decision about whether to join or withdraw from a particular third-party prescription program.
2. MPA and BMDA cannot allow any of their meetings to be used as a place where individual pharmacists meet and discuss whether they will join or withdraw from a particular third-party program. This means that, even when we call a meeting to discuss a different matter, if the topics discussed at the meeting turns to a discussion of participation in third-party reimbursement programs, the leadership and/or staff in charge of that meeting must take action.

If one pharmacist makes a statement like "I refuse to partici-

pate in XYZ Plan!" then that pharmacist will be ejected from the meeting. If two or more people make similar statements, then the meeting must be immediately ended.

We cannot and will not tolerate any use of formal or informal meetings as forums for discussion of third-party program participation.

3. MPA and BMDA cannot act as an intermediate party which relays information to pharmacists about whether other pharmacists have decided to join, not join, or withdraw from a particular third-party prescription program.

For example, if a pharmacist mentions to me in passing that she has decided not to participate in a new HMO plan, then I am prohibited from passing that information on in any form to any other pharmacist. Likewise, I cannot tell her that another pharmacist I know has already signed the contract and joined the HMO plan. This requirement applies to all officers, trustees, leaders, staff, employees, representatives, etc. of both organizations. Our consent order requires that this be in effect for the five years from March 1, 1994 until March 1, 1999.

4. MPA and BMDA cannot provide comments or advice to any pharmacist or pharmacy regarding the desirability or appropriateness of participating in any third-party prescription program. In other words, we cannot write newsletters, articles, memos, or engage in discussions with any pharmacist or pharmacy representative about whether they should join, not join or withdraw from any third-party prescription program.

This prohibition includes not only obvious statements such as "do not join the new ABC insurance company program" but also related statements where the same intention is implied, such as "the

new ABC insurance company program is really lousy."

The consent order expressly authorizes MPA and BMDA to provide "purely factual information describing the terms and conditions of any participation agreement or operations of any third-party payers." We can report that ABC-Rx has filed for bankruptcy; we cannot report that pharmacists should quit filling ABC-Rx prescription. We can report that ABC-Rx has an AWP-99% reimbursement rate; we cannot report that AWP-99% is too little and ABC-Rx should be refused. All reporting of factual information must be and will be carefully to assure that it stays completely dispassionate and does not -- even indirectly -- encourage pharmacists or pharmacies to join, not join or withdraw from a third-party program.

What informational steps are BMDA and MPA required to take?

To completely inform their members about the consent agreement, BMDA and MPA agreed to comply with several information and reporting requirements. These are:

1. A copy of the consent order and the complaint issued by the FTC must be mailed by first class mail by May 1, 1994 to all members of BMDA and MPA.
2. Publish a copy of the consent order and the complaint in an issue of *The Maryland Pharmacist* by June 1, 1994.
3. Provide each new member of either organization with a copy of the consent order when they are accepted for membership. This must be done for five years from March 1, 1994.
4. BMDA and MPA must file a verified, written report with the Commission before June 1, 1994 showing how we have complied and are complying with the terms of the consent order. Then, for the next five years, we must file an annual report with the FTC every March 1.
5. BMDA and MPA must maintain

records which substantiate compliance with the consent order. If the FTC requests to inspect those records, we must permit them to do so. This includes any and all copies of third-party prescription program participation agreements.

6. BMPA and MPhA must tell the FTC at least a month in advance if either organization moves, merges with another organization, or changes its name. The FTC needs to know this so that the FTC can assure continued compliance with the consent order.

Summary

In signing this consent order, neither the Maryland Pharmacists Association nor the Baltimore Metropolitan Pharmacists Association have conceded that any laws were violated. In order to avoid the extraordinary costs of litigating

against the FTC, and avoid the risk of losing such a case even though we believe we did nothing wrong, MPhA and BMPA decided to "settle out of court."

If you have any questions about the consent order, the complaint, or MPhA's response to this entire issue, please don't hesitate to contact me or the MPhA staff at (410) 727-0746 or toll-free for members at (800) 833-7587.

R

Editor's Note: Because of the importance of the Federal Trade Commission's consent order with the Maryland Pharmacists Association, this month's continuing education quiz features information on the FTC complaint, the signed consent order, and the background presented in this article. The quiz appears on page 24 of this issue of *The Maryland Pharmacist* and provides one hour of Maryland Board of Pharmacy

continuing education credit. The CE quiz is free to MPhA members for this issue only. Non-members must still pay \$10.00. To take advantage of this special member benefit, follow the instructions appearing at the top of page 24, complete the quiz, and return it to the MPhA offices at 650 West Lombard Street, Baltimore, Maryland 21201-1572.



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The Complaint

Against the BMPA and the Maryland Pharmacists Association



United States of America Before Federal Trade Commission

In the Matter of

Baltimore Metropolitan Pharmaceutical Association, Inc., Docket No. 9262
a corporation, and

Maryland Pharmacists Association, Inc.,
a corporation.

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that the Baltimore Metropolitan Pharmaceutical Association and the Maryland Pharmacists Association, Inc. (hereinafter sometimes referred to as "BMPA" and "MPhA," respectively, or as "respondents," collectively), have violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

Paragraph One

Respondent Baltimore Metropolitan Pharmaceutical Association, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Maryland. Respondent Maryland Pharmacists Association, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Maryland. Both respondents have their offices and principal places of business located at 650 West Lombard Street, Baltimore, Maryland 21201. Respondents are associations of pharmacists who practice or reside in the State of Maryland. In 1988, respondents were, and still are affiliated.

Paragraph Two

Respondents share common offices and staff, including a common Executive Director. Most of respondent BMPA's members are also members of respondent MPhA.

Paragraph Three

Members of respondents hold ownership interests in or manage pharmacy firms that, except to the extent that competition has been restrained as alleged herein, have been and are now in competition with each other and with other pharmacy firms and other health care providers in the State of Maryland.

Paragraph Four

Respondents' general business or activities, and the acts and practices described below, are in or affect commerce, as "commerce" is defined in the Federal Trade Commission Act.

Paragraph Five

Respondents are and have been, at all times relevant to this complaint, corporations organized for the profit of their members within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

Paragraph Six

Customers often receive prescriptions through health benefit programs under which a third-party payer compensates the pharmacy directly for the prescription according to a predetermined formula ("prescription drug benefit plan"). A pharmacy that has agreed to accept reimbursements under this formula is called a "participating pharmacy." One of the primary consumer benefits of such programs is that the customer is required to pay only a small set amount, known in the industry as the "customer co-pay," to the participating pharmacy for each prescription, regardless of the actual price of the prescription.

Paragraph Seven

PCS Plan #354 ("Plan") was a prescription drug benefit plan made available by the City of Baltimore, Maryland ("City") to its employees, its retirees, and their dependents. There were approximately 100,000 beneficiaries covered by the plan in 1988. Between August 1, 1987, and June 30, 1989, The Prudential Insurance Company of America ("Prudential") insured the Plan, and PCS, Inc. ("PCS"), administered the Plan. While the contract between the City and Prudential did not set the reimbursement terms of the Plan, thus permitting Prudential to change the reimbursement rate at any time, the contract did require Prudential to have at least 100 participating pharmacies within the City.

Paragraph Eight

Pharmacies were initially solicited to participate in the Plan for the period August 1, 1987, to June 30, 1989. Participating pharmacies in the Plan accepted as payment in full a reimbursement of the ingredient cost of the drug and a professional fee for dispensing the drug. A portion of the professional fee was in the form of the customer co-pay. The Plan set the Average Wholesale Price ("AWP") of the drug as the upper limit for the reimbursement of the ingredient cost of drugs dispensed. Prior to August 15, 1988, most pharmacies in the State of Maryland billed PCS at AWP for the drugs dispensed under the Plan.

Paragraph Nine

In 1988, respondents' members held ownership interests in pharmacy firms that participated in many prescription drug benefit plans offered by third-party payers, including the Plan as it existed prior to August 15, 1988. These pharmacy firms would have suffered a significant loss of customers had their competitors participated in the Plan when they were not participating.

Paragraph Ten

On August 5, 1988, PCS sent letters to all of the pharmacies participating in the Plan announcing that, on August 15, 1988, Prudential would reduce the upper limit of the reimbursement rate for ingredient costs for drugs to AWP minus 10%. The proposed reduction was intended to minimize costs by reducing the price paid the pharmacies for serving City employees, retirees, and their dependents, while offering a reimbursement rate high enough to attract a sufficient number of pharmacies to ensure that there were at least 100 participating pharmacies within the City.

Paragraph Eleven

Absent collusion between or among pharmacy firms, each pharmacy firm would have decided independently whether to participate in the Plan, and the City would have enjoyed the benefits of competition among pharmacy firms.

Paragraph Twelve

On about August 12, 1988, respondents' members began informing respondents of the proposed reduction in the Plan's reimbursement rate. Respondents held meetings where the reimbursement rate reduction and possible action in response to it were discussed. Respondents communicated to pharmacists the need for pharmacies within the City to refuse to participate in the Plan so that Prudential would be in violation of its contractual obligation to have at least 100 participating pharmacies within the City and thus be forced to raise the reimbursement rate to its original level. Respondents requested pharmacists to notify them if their pharmacies did not intend to participate in the Plan. Respondents kept a list identifying those pharmacies that intended to stop participating in the Plan and communicated this information to their members. Through these exchanges of information, respondents' members were informed that a sufficient number of pharmacies had agreed to stop participating in the Plan to reduce the number of participating pharmacies within the City to below 100.

Paragraph Thirteen

At some point in late September or early October, 1988, many of respondents' members agreed to stop participating in the Plan as of November 1, 1988. Respondent BMPPA sent a letter to City pharmacists in late October, 1988, which urged member pharmacists to "follow through with your November 1 commitment to no longer accept discounted AWP reimbursements." By October 31, 1988, more than 75 pharmacies operated by member pharmacists within the City had agreed to stop participating in the Plan. On November 1, 1988, these pharmacies began to boycott the Plan.

Paragraph Fourteen

As a result of the activities described above and the resulting boycott, Prudential was placed in violation of its contract with the City and was forced to raise the reimbursement rate back to AWP on November 5, 1988.

Paragraph Fifteen

Respondents have restrained competition among pharmacy firms by conspiring with their members and with others, and by acting as a combination of their members, to increase the price paid to participating pharmacies under the Plan.

Paragraph Sixteen

The combination or conspiracies and the acts and practices described above have unreasonably restrained competition among pharmacists and pharmacies in the State of Maryland, and have injured consumers in the following ways, among others:

A. Price competition among pharmacy firms with respect to prescription drug benefit plans has been and continues to be reduced; and

B. The cost of providing prescription drug benefit plans was increased.

Paragraph Seventeen

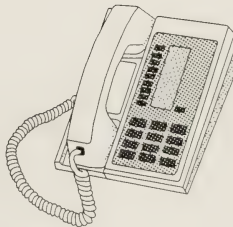
The combination or conspiracies and the acts and practices described above constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act. The combination or conspiracies, or the effects thereof, are continuing, will continue, or will recur in the absence of the relief herein requested. **R**

Editor's Note: This complaint against the Baltimore Metropolitan Pharmacists Association and the Maryland Pharmacists Association was filed by the Federal Trade Commission on September 28, 1993. Publication of this document satisfies the requirement of the Consent Order Part III, Section C.

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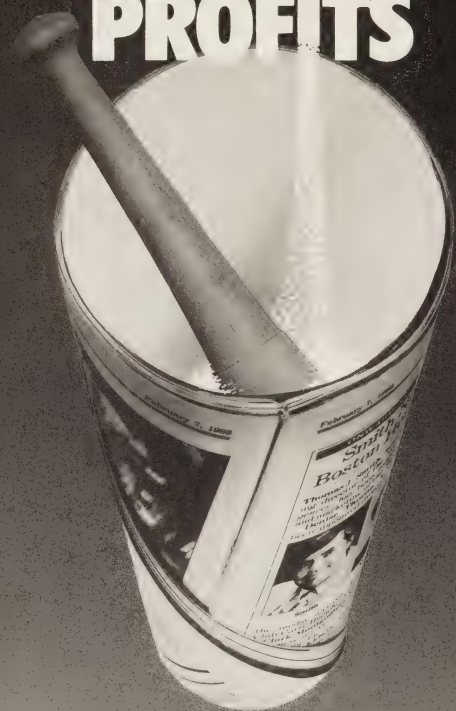
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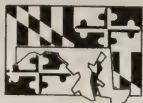
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The Consent Agreement

Between the FTC, BMPA and the Maryland Pharmacists Association



United States of America Before Federal Trade Commission

In the Matter of

**Baltimore Metropolitan Pharmaceutical
Association, Inc.,**
a corporation, and

Docket No. 9262

Agreement Containing
Consent Order to
Cease and Desist

Maryland Pharmacists Association, Inc.,
a corporation.

The agreement herein, by and between the Baltimore Metropolitan Pharmaceutical Association, Inc., a corporation, and the Maryland Pharmacists Association, Inc., a corporation, (hereinafter sometimes referred to as "BMPA" and "MPHA," respectively, or as "respondents," collectively), by their duly authorized officers, and their attorney, and counsel for the Federal Trade Commission, is entered into in accordance with the Commission's Rule governing consent order procedures. In accordance therewith the parties hereby agree that:

1. Respondent BMPA is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Maryland. Respondent MPHA is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Maryland. Both respondents have their offices and principal places of business at 650 West Lombard Street, Baltimore, Maryland 21201.
2. Respondents have been served with a copy of the complaint issued by the Federal Trade Commission charging them with violation of Section 5 of the Federal Trade Commission Act.
3. Respondents admit all the jurisdictional facts set forth in the Commission's complaint in this proceeding.
4. Respondents waive:
 - (a) Any further procedural steps;
 - (b) The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;
 - (c) All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement; and
 - (d) Any claim under the Equal Access to Justice Act.
5. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it will be placed on the public record for a period of sixty (60) days and information with respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify respondents, in which event it will take such action as it may consider appropriate, or issue and serve its decision, in disposition of the proceeding.

6. This agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in said copy of the complaint issued by the Commission.

7. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 3.25(f) of the Commission's Rules, the Commission may, without further notice to respondents, (1) issue its decision containing the following order to cease and desist in disposition of the proceedings, and (2) make information public in respect thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the U.S. Postal Service of the decision containing the agreed-to-order to respondent's address, as stated in this agreement, shall constitute service. Respondents waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or to contradict the terms of the order.

8. Respondents have read the complaint and the order contemplated hereby. They understand that once the order has been issued, they will be required to file one or more compliance reports showing that they have fully complied with the order. Respondents further understand that they may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

Order - Part I

FOR PURPOSES OF THIS ORDER, the following definitions shall apply:

A. "BMPA" means the Baltimore Metropolitan Pharmaceutical Association, Inc., and its directors, committees, officers, agents, representatives, employees, successors and assigns;

B. "MPhA" means the Maryland Pharmacists Association, Inc., and its directors, committees, officers, agents, representatives, employees, successors and assigns;

C. "Third-party payer" means any person or entity that provides a program or plan pursuant to which such person or entity agrees to pay for prescriptions dispensed by pharmacies to individuals described in the plan or program as eligible for coverage ("Covered Persons"), and includes, but is not limited to, health insurance companies; prepaid hospital, medical, or other health service plans, such as Blue Cross and Blue Shield plans; health maintenance organizations; preferred provider organizations; prescription service administrative organizations; and health benefits programs for

government employees, retirees and dependents;

D. "Participation agreement" means any existing or proposed agreement, oral or written, in which a third-party payer agrees to reimburse a pharmacy firm for the dispensing of prescriptions drugs to Covered Persons, and the pharmacy firm agrees to accept such payment from the third-party payer for such prescriptions dispensed during the term of the agreement;

E. "Pharmacy firm" means any partnership, sole proprietorship or corporation, including all of its subsidiaries, affiliates, divisions and joint ventures, that owns, controls or operates one or more pharmacies, including the directors, officers, employees, and agents of such partnership, sole proprietorship or corporation, as well as the directors, officers, employees, and agents of such partnership's, sole proprietorship's or corporation's subsidiaries, affiliates, divisions and joint ventures. The words "subsidiary," "affiliate," and "joint venture" refer to any firm in which there is partial (10% or more) or total ownership or control between corporations.

Part II

IT IS ORDERED that BMPA and MPhA, directly, indirectly, or through any corporation or other device, in or in connection with their activities in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, forthwith cease and desist from:

A. Entering into, threatening or attempting to enter into, organizing, encouraging, continuing, cooperating in, or carrying out any agreement between or among pharmacy firms, either express or implied, to withdraw from, threaten to withdraw from, refuse to enter into, or threaten to refuse to enter into, any participation agreement;

B. For a period of five (5) years after the date this order becomes final, continuing a formal or informal meeting of representatives of pharmacy firms after 1) any person makes any statement concerning one or more firms' intentions or decisions with respect to entering into, refusing to enter into, threatening to refuse to enter into, participating in, threatening to withdraw from, or withdrawing from any existing or proposed participation agreement and BMPA or MPhA fails to eject such person from the meeting, or 2) two persons make any such statements;

C. For a period of five (5) years after the date this order becomes final, communicating in any way to, or soliciting in any way from, any pharmacist or pharmacy firm any information concerning any pharmacy firm's intention or decision with respect to entering into, refusing to enter into, threatening to refuse to enter into, participating in, threatening to withdraw from, or withdrawing from any existing or proposed participation agreement; and

D. For a period of five (5) years after the date this order becomes final, providing comments or advice to any pharmacist or pharmacy firm on the desirability, profitability or appropriateness of participating in any existing or proposed participation agreement. However, nothing in this paragraph shall prohibit BMPhA or MPhA from communicating purely factual information describing the terms and conditions or any participation agreement or operations of any third-party payers.

Provided that nothing in this order shall be construed to prevent BMPhA or MPhA from exercising rights protected under the First Amendment to the United States Constitution to petition any federal, state, or local government executive agency or legislative body concerning legislation, rules, programs, procedures, or plans, or to participate in any federal, state, or local administrative or judicial proceeding.

Part III

IT IS FURTHER ORDERED THAT:

A. BMPhA distribute by first-class mail a copy of this order and the accompanying complaint to each of its members within sixty (60) days after the date this order becomes final;

B. MPhA distribute by first-class mail a copy of this order and the accompanying complaint to each of its members that is not also a member of BMPhA, within sixty (60) days after the date this order becomes final;

C. MPhA publish this order and the accompanying complaint in an issue of *The Maryland Pharmacist* or in any successor publication published no later than ninety (90) days after the date this order becomes final, in the same type size normally used for articles that are published in *The Maryland Pharmacist* or successor publication;

D. BMPhA and MPhA, for a period of five (5) years after the date this order becomes final, provide each new BMPhA and MPhA member with a copy of this order at the time the member is accepted into membership of BMPhA or MPhA;

E. BMPhA and MPhA each file a verified, written report with the Commission within ninety (90) days after the date this order becomes final, and annually thereafter for five (5) years on the anniversary of the date this order becomes final, and at such other times as the Commission may, by written notice to BMPhA or MPhA, require, setting forth in detail the manner and form in which it has complied and is complying with the order;

F. BMPhA and MPhA for a period of five (5) years after the date this order becomes final, maintain and make available to Commission staff, for inspection and copying upon reasonable notice, records adequate to describe in detail any action taken in connection with the activities covered by Parts II and III of this order, including, but not limited to, all documents generated by

BMPhA or MPhA or that come into BMPhA's or MPhA's possession, custody, or control regardless of source, that embody, discuss or refer to the terms or conditions of any participation agreement; and

G. BMPhA and MPhA notify the Commission at least thirty (30) days prior to any proposed change in BMPhA or MPhA such as, assignment or sale resulting in the emergence of a successor corporation or association, change of name, change of address, dissolution, or any other change that may affect compliance with this order.

Signed 2 November 1993 by:

James B. Culp, President
Baltimore Metropolitan Pharmaceutical Association, Inc.

Howard R. Schiff, President
Maryland Pharmacists Association

Joseph S. Kaufman
Counsel for Respondents

John R. Hoagland, Malcom Catt, Commission Counsel
Federal Trade Commission

Michael D. McNeely, Assistant Director
Federal Trade Commission

James C. Egan, Jr., Director for Litigation,
Bureau of Competition
Federal Trade Commission

Mary Lou Steptoe, Acting Director
Bureau of Competition
Federal Trade Commission

Editor's Note: This consent order between the Baltimore Metropolitan Pharmacists Association, Maryland Pharmacists Association and Federal Trade Commission was accepted as final on March 1, 1994 subsequent to the November 2, 1993 signing and the sixty (60) day public comment period. Publication of this document in this, the April 1994 issue of *The Maryland Pharmacist*, is to satisfy the requirement of this Order, Part III, Section C. This article appears in typeface Tiempo Roman, Tiempo Roman Bold, and Tiempo Roman Italic at a typesize value of 10 points.

R

What's Your Pharmacoeconomics I.Q.?

Test yourself! Answers at bottom of page.

1. Outpatient prescription medicines account for approximately what percent of total health care spending?
a. 5% b. 10% c. 15% d. 20%
2. How many years of patent life typically remain once a new drug is approved for marketing?
a. 17 b. 10-12 c. 3-5 d. 5-7
3. Which amount is the closest to the actual cost of dispensing a prescription in a full-service pharmacy?
a. \$2.00 b. \$3.35 c. \$6.00 d. \$1.25
4. Out of every ten new drugs marketed, on average, how many achieve sufficient revenue to cover costs and make a profit?
a. 8 b. 2 c. 6 d. 1
5. Considering drug prices and manufacturing wages in the U.S. & Mexico, how long do Mexicans work compared to Americans to pay for Rx drugs?
a. same # hours b. Half as long c. more than twice as long
6. What is the current estimated cost of bringing a new drug to market?
a. \$175 million b. \$359 million c. \$500 million d. \$100 million
7. Which component of health care costs are patients most aware of because they pay out of pocket?
a. physician b. prescription c. hospital d. emergency room
8. What percent of sales, on average, is spent on research by research-intensive pharmaceutical manufacturers?
a. 25 b. 16 c. 8 d. 11
9. Total health care expenditures have risen to almost 13% of GNP since 1960. How have pharmaceutical costs behaved as a % of GNP during that period?
a. risen to 3% b. fallen to 0.5% c. held nearly constant under 1%
10. If pharmaceutical industry profits were eliminated, how much would this reduce total national health care costs?
a. 3% b. 5% c. less than 1% d. 10%

Answers: 1 a. 5%; 2 d. 5-7; 3 c. \$6.00; 4 b. 2; 5 c. more than twice as long; 6 b. \$359 million; 7 b. prescription; 8 b. 16; 9 c. held nearly constant under 1%; 10 c. less than 1%

Lilly

Effort Involved in Processing Prescriptions

Maryland Community Pharmacists' Perceptions

Sylvie Poirier, Ph.D., David A. Knapp, Ph.D., Donald O. Fedder, D.P.H., and Stuart M. Speedie, Ph.D.



Results described in this paper are extracted from the doctoral dissertation in Pharmacy Administration at the University of Maryland of the first author. The authors would like to acknowledge the financial support from Marion Merrell Dow, Inc. and the assistance of the Center for Pharmacy Management of Mercer Southern School of Pharmacy. The authors would like to thank the Maryland pharmacists who graciously responded to the questionnaire and without whom this project could not have been possible.

Processing prescriptions is the core of the community pharmacy profession.¹ The role of pharmacists in processing prescriptions encompasses a continuum of possible services.^{2,4} Although some prescriptions may require a minimum of services, expanded services may be necessary to safely and adequately process some others. The extent of the services provided may differ substantially based on the characteristics of the medication or the attributes of the patient to whom the prescription is given.

Pharmacists' activities involved in processing prescriptions have been well documented by workload measurement studies done in the 1970's, but no effort has been made to relate pharmacists' workload to characteristics of the prescriptions processed.⁵⁻⁹ The promotion of the concept of pharmaceutical care encourages a more "interventionist" practice. Thus, it becomes essential that the impact on pharmacists' workload of pharmaceutical care which calls for the prevention and resolution of drug-related problems, be better understood. Reimbursing pharmacists a fixed fee for processing various prescriptions (no matter the extent of the services required) may be an oversimplification of pharmacists' work if the effort involved differ significantly among prescriptions. The primary goal of this study was to measure the influence of prescription characteristics on pharmacists' perception of effort (work)¹ required to process prescriptions.

The characteristics of the prescription investigated were the following: drug class, payment method for the prescription, patient age, prescription status (new or refill), and presence and category of drug-related problems (DRPs).

Methodology

In the fall 1992, questionnaires were sent to 1,524 community pharmacists residing and practicing in the state of Maryland. Each pharmacist was asked to evaluate five prescriptions and their corresponding patient profiles. The order of the five prescriptions varied from one questionnaire to the other. The five prescriptions (R) were:

- R 1 New prescription with no drug-related problem
- R 2 New prescription with an excessive dosage
- R 3 New prescription with a drug interaction
- R 4 Refill prescription with no drug-related problem
- R 5 Refill prescription for a non-compliant patient

The drug class (digitalis preparation or non-steroidal anti-inflammatory drug), payment method for the prescription (out-of-pocket or Medicaid), and patient age (adult or elderly) were kept constant for the five prescriptions in a questionnaire. Each pharmacist was assigned randomly to one of the eight versions of the questionnaire (See Table 1).

On a horizontal line with nine equal intervals, respondents were asked to indicate how much effort (10 to 100 units) would be necessary if they had to process the prescriptions.

The anchors affixed on the scale were the following: very little (10 units), moderate (55 units), and very much (100 units).

Description of the Respondents

Of the 1,524 questionnaires mailed, 213 undeliverable questionnaires were returned by the postal service and 61 pharmacists who returned the questionnaires were not eligible. The final sample contained 1,244 eligible pharmacists. Of these, 601 completed and returned the questionnaire for a net response rate of 48.3%. The average age of the respondents was 46 years and 76% of the respondents were male. More

than half (55%) of the respondents worked in a chain. On the average 156 prescriptions were filled per day, of which 57% were reimbursed by third-party payers. Almost all pharmacies were equipped with computerized patient profiles (98%) and computerized drug interaction screening programs (95%).

Results

Effort scores for processing both new prescriptions with a drug-related problem such as excessive dose (R 2) and drug interaction (R 3) were perceived as requiring approximately 2.5 times the effort scores of their counterpart without a drug-related problem (R 1). Between moderate and very much effort was perceived necessary to process a new prescription with a drug-related problem. Between very little and

moderate level of effort was perceived necessary to process a new prescription without a drug-related problem.

Effort required to process both new prescriptions with a drug-related problem (R 2 and R 3) was significantly higher than effort required to process a refill prescription for a non-compliant patient (R 5). Compared to new or refill prescriptions without a DRP, effort scores were approximately double (1.9 times) for a refill prescription for a non-compliant patient.

Figure 1 illustrates effort scores perceived necessary to process R 1 to R 5. It summarizes the influence of the presence and category of drug-related problems on the perception of effort required to process prescriptions.

Patient age and payment method did not significantly influence pharmacists' perception of the effort required to process a prescription. A NSAID (flurbiprofen) prescription was perceived to require slightly more effort than a prescription for a cardiovascular drug (digoxin). These findings were unexpected and deserve some comments.

In the patient profiles and prescriptions used in the questionnaire, medications for elderly and adults were identical. If one considers that the extra effort required to process prescriptions for the elderly may mostly result from more complex pathologies and an increased number of pharmacotherapies, it is understandable that

List of Eight Versions of the Questionnaire

Q #	Drug	Patient age	Payment method
Q 1.	digoxin	elderly	third-party payer
Q 2.	flurbiprofen	elderly	third-party payer
Q 3.	digoxin	elderly	out-of-pocket
Q 4.	NSAID	elderly	out-of-pocket
Q 5.	digoxin	adult	third-party payer
Q 6.	NSAID	adult	third-party payer
Q 7.	digoxin	adult	out-of-pocket
Q 8.	NSAID	adult	out-of-pocket

Table 1

A New Member Benefit!

Maryland Pharmacists Association and Americom Cellular

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for all MPhA Members**

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Peak Minutes	\$ 0.37 per Minute
Off Peak	\$ 0.17 per Minute

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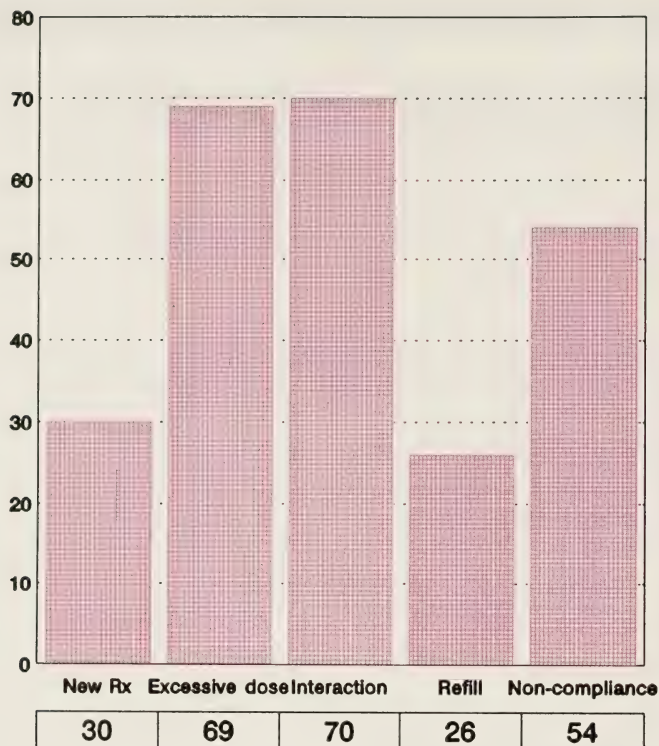


Figure 1
Effort Scores Required to Process Prescriptions

no difference was found in effort scores between elderly and adults. From these results, it was determined that the age of the patient *per se* is not a determining factor influencing the effort required to process a prescription. Other factors associated with older age, such as physical and cognitive impairments, polypharmacy, more complex therapy, higher susceptibility to drug-related problems may be the determinant factors.

It was expected that effort scores would be greater for prescriptions processed for Medicaid patients than prescriptions processed for patients who pay for their prescriptions out-of-pocket. The reimbursement of a prescription by a third-party payer has an impact on the administrative tasks of the pharmacists (claim processing, eligibility of patient, drug coverage, modification of unapproved claims)

and not on his clinical activities. In the questionnaire, the parameters drug class, patient age, and payment method of the five prescriptions were identical with the exception of the prescription status (new or refill) and the presence and category of drug-related problems, which impact directly on clinical activities of the pharmacist. In this context, it is probable that when answering the questionnaire, pharmacists were more concerned with the clinical aspects of their work and not the administrative ones. For example, three pharmacists mentioned they did not take any Medicaid paperwork into consideration in their answers. Pharmacists were asked to consider the effort from the time the patient presents the prescription to the time the patient leaves the pharmacy. Most of the administrative tasks are

performed after the patient leaves the pharmacy. This may partly explain the results.

Regarding drug class, pharmacists are more familiar with digoxin than flurbiprofen. While flurbiprofen was put on the market in 1988, digoxin has been prescribed for over 50 years. Digoxin is also more frequently prescribed than flurbiprofen. In 1991, Lanoxin was ranked the 4th most frequently dispensed drug and Ansaïd was ranked the 84th most frequently dispensed drug.¹⁰ Incidentally, one pharmacist commented that Ansaïd 50 mg was rarely prescribed.

Discussion

The recognition of pharmacists' effort necessary to provide different categories of pharmaceutical services has implications for the issue of compensating pharmacists for these expanded pharmaceutical services. Some pharmacists are currently providing extensive pharmaceutical services while others are offering minimal services. All receive the same dispensing fee. The determination of pharmacists' effort required to process prescriptions with a drug-related problem compared to prescriptions without a drug-related problem may be considered as a step toward the development of an equitable compensation schedule for pharmacists providing pharmaceutical care. According to the results, were identified three categories of pharmaceutical services: (1) prescriptions without a drug-related problem (1 unit of effort); prescriptions for non-compliant patients (1.9 units of effort); and prescriptions with a drug-related problem that require an intervention with the physician (2.5 units of effort) (See Figure 2).

Inequities associated with a fixed fee could be lessened by compensating pharmacists based on a relative value scale (RVS) of effort associated with the provision of pharmaceutical services. The application of a relative value scale in

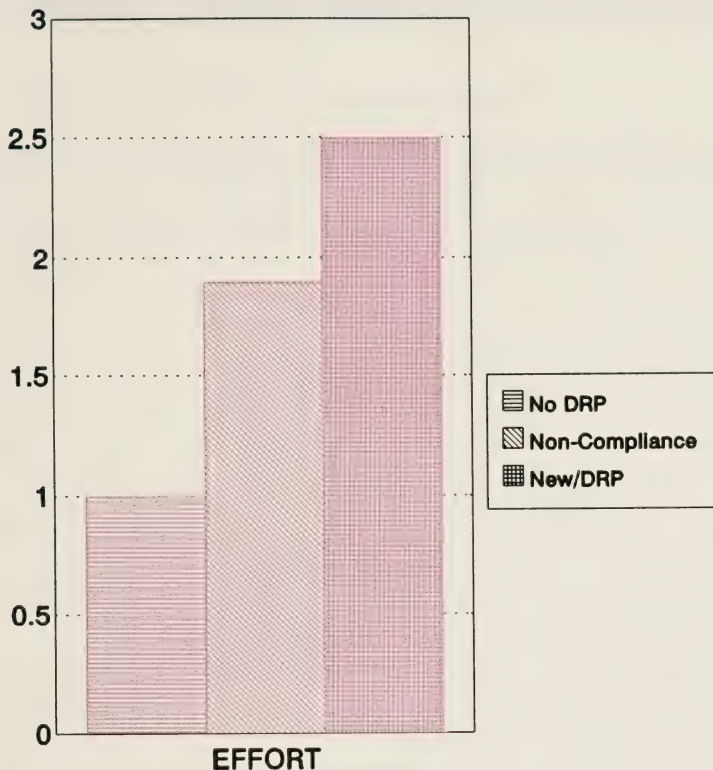


Figure 2

Relative Value Scale of Effort to Process Prescriptions

the development of a compensation scheme for the prevention or resolution of drug-related problems (cognitive services) would provide a suitable mechanism for separating reimbursement for cognitive services from dispensing while not disturbing the current reimbursement procedures. Moreover, it is believed that it would stimulate the provision of more comprehensive and innovative services.¹¹

In conclusion, pharmaceutical care improving patient outcomes should be the essence of a policy for compensating pharmacists for providing pharmaceutical services. Accordingly, if pharmacists were compensated for the prevention and resolution of drug-related problems, the effort required to provide the professional services should be considered. **R**

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About the Authors

Sylvie Poirier is Assistant Professor, Faculty of Pharmacy, University of Montreal. David Knapp is Dean of the University of Maryland School of Pharmacy in Baltimore. Donald Fedder and Stuart Speedie are professors, Department of Pharmacy Practice and Science at the University of Maryland School of Pharmacy.

Continuing Education Quiz

April 1994 -- The FTC Consent Order

This month's questions are taken from the articles about the Federal Trade Commission and the Maryland Pharmacists Association that appear in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members \$10.00). The completed quiz for this issue must be received by September 30, 1994. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

Social Security Number _____

Address _____

City/State/ZIP Code _____

1. The Federal Trade Commission's investigation and complaint against MPhA and BMDA arose from:
 - a. Express Scripts management of the Baltimore City Employee Prescription program
 - b. Prudential's unilateral decision to reduce reimbursement to participating pharmacies
 - c. PCS' unilateral decision to reduce reimbursement to participating pharmacies
 - d. Blue Cross' decision to reduce reimbursement to participating pharmacies
2. By signing a consent order with the FTC, the MPhA admitted that they were guilty of all alleged anti-trust allegations.
 - a. true
 - b. false
3. MPhA's decision to sign a consent order with the FTC was based on the following factors:
 - a. limited financial resources
 - b. limited staff resources
 - c. potentially lengthy court time and attorney fees
 - d. all of the above
4. Under the federal anti-trust laws, associations of pharmacists are:
 - a. competitors engaged in commerce
 - b. professionals engaged in commerce
 - c. potential competitors engaged in commerce
 - d. potential professionals engaged in commerce
5. MPhA can advise its members to sign or not sign third-party pharmacy participation contracts.
 - a. true
 - b. false
6. The signed consent order requires all of the following informational activities except:
 - a. sending all MPhA members a copy of the order
 - b. publishing a copy of the consent and complaint
 - c. making monthly reports to the FTC
 - d. maintaining documentation to show compliance
7. The FTC consent order will expire on:
 - a. March 1, 1994
 - b. June 1, 1994
 - c. March 1, 1999
 - d. March 1, 2000
8. A pharmacist at the Annual Convention stands up and states that all MPhA members should boycott a new HMO program. What happens?
 - a. the pharmacist is charged with an anti-trust violation and fined \$10,000
 - b. the pharmacist is asked to explain his reasons why members should boycott the program
 - c. the pharmacist is ejected from the meeting
 - d. the pharmacist is asked to write an article for the next issue of *The Maryland Pharmacist* about the HMO's reimbursement program
9. Another pharmacist at the Annual Convention agrees. She encourages all pharmacists to stand up to the HMO by refusing to participate. What happens?
 - a. both pharmacists are charged with an anti-trust violation and fined \$10,000 each
 - b. the pharmacist is asked to explain her reasons why members should boycott the program
 - c. MPhA immediately closes the meeting
 - d. both pharmacists are asked to collaborate on an article for the next issue of *The Maryland Pharmacist* about the HMO's reimbursement

Pharmacy Technicians and Pharmaceutical Care

Carol A. Roby, Pharmacy Student, UMAB School of Pharmacy

This article is the fourth in a series written by pharmacy students in the first course of the new entry-level Pharm.D. program at the University of Maryland School of Pharmacy. PHAR 516 (Pharmacy Practice and Education) is an introductory course which exposes the students to pharmacy practice, pharmaceutical sciences, ethics, communication, and critical thinking. One of the class assignments was to write a critical evaluation on one of three topics: pharmaceutical care, pharmacy technicians, or mail-order pharmacy. This course was developed by MPhA Past President Ilene Zuckerman with the assistance of MPhA member and graduate student Diane McNalley.

Pharmacy, as a profession, is at a critical cross road. The path chosen will decide if pharmacists embrace the pharmaceutical care model and become clinically accepted, fully integrated health care professionals, or fade away into the background, continuing to perform merely technical dispensing tasks.^{1,2,3,4,5,6,7}

There are several barriers that must be overcome before the concept of pharmaceutical care can become a reality, including:

- A system of reimbursement for consultations and interventions, *ie.*, the pharmacist's cognitive skills, must be implemented^{1,2,3,4,8};
- The public and other health care professionals must begin to value and expect the clinical involvement of the pharmacist^{2,4};
- The current drug distribution model must be re-evaluated and updated^{6,8,9,10,11};
- Pharmacists must practice to their full potential, accepting their responsibility as the managers of drug use in society, and providing a professional level of service that more appropriately reflects their knowledge and training^{2,4,5,12,13,14,15};
- Information exchange systems must be updated and improved^{6,9,11}; and, most crucially,
- The use and duties of support personnel must be well-defined and expanded.^{9,11,12,14,15,16,17}

The topic of expanded duties for support personnel, also known as pharmacy technicians, is highly debated within the profession. Many agree that the profession cannot grow and evolve into the pharmaceutical care model without increased reliance

on highly trained support personnel for the completion of routine, manipulative, non-judgmental duties.^{6,9,15,17,18} There are, however, pharmacists that fear an expansion of the technicians' duties and responsibilities would degrade the profession as a whole, rendering them obsolete and unemployed.^{19,20}

The use of expanded duty paraprofessionals is not a new idea. The professions of medicine, dentistry and law have all successfully integrated the use of specially trained support personnel to the enhancement, not detriment, of their professions.¹² Physicians' assistants, nurse practitioners, dental hygienists and paralegals all play important, accepted, well-defined roles in their respective fields.^{21,22} They free the professionals from the routine,

Unfortunately, pharmacy in the United States has not afforded technicians the same opportunities for expanded duties and increased responsibilities that support personnel in other professions have enjoyed

repetitive tasks that must be done to facilitate the practice, but do not require a professional education to complete; allowing the professional to practice more efficiently and at a level more consistent with his/her education and training. In this way, the use of supportive personnel

complements the professional; it does not *replace* the professionals.

Pharmacy has made use of support personnel for over 25 years, and they are an increasingly important part of pharmacy practice today.^{3,13,20} Unfortunately, pharmacy in the United States has not afforded technicians the same opportunities for expanded duties and increased responsibilities that support personnel in other professions have enjoyed. In other countries, and even in our own military, pharmacy technicians have a long history of competency in expanded duty roles.^{4,20,23} In fact the military use of support personnel has shown that well-trained technicians can function reliably and independently in many practice situations.^{4,23} Perhaps it is time for pharmacy in the United States to learn from and emulate the well-defined hierarchies employed in the practice of pharmacy both abroad and in the military.

The literature contains many diverse examples of pilot programs showing that the expansion of the technician's training and duties not only increases the efficiency of pharmacy services, but gives the pharmacist more time to function at the professional level: to educate, counsel patients, conduct clinical monitoring, participate in rounds, and consult with other health care professionals.^{24,25,26,27} As a result, there is an increase in the quality assurance protocols in place; the dispensing error rates for technicians were either equal to or less than that of pharmacists.^{13,24,26} These pilot programs show that when technicians are used to their full potential, not

only are pharmacists able to expand their professional duties, but pharmacy services as a whole can be increased in a cost effective way, without compromising patient safety.

*The increased use of
well trained, expanded
duty technicians
will complement and
enhance the
pharmacist's role
as a health care
provider, not
supersede it*

Several authors have suggested that pharmacists who are afraid that they will be replaced by expanded duty technicians, must only be working at the level of a technician themselves.^{4,12,17,20} As the role of a pharmacy technician evolves and expands, so must the role of the pharmacist.^{4,10} A basic tenet of the pharmaceutical care model is for pharmacists to become directly involved at the clinical level in patient care, to ensure a desirable therapeutic outcome.^{9,11} Therefore, if the proper hierarchy is established, as it has been in the professions mentioned above, as well as in international and military pharmacy, the increased use of well trained expanded duty technicians will complement and enhance the pharmacist's role as a health care provider, not supersede it.

Concern about patient safety due to a lack of standardized training has

also been voiced.⁴ A commonality to the successful use of support personnel in both the pilot programs and the military, is the application of rigorous, standardized training programs.^{14,20,23,26} The issues regarding technician training, certification, and/or licensure are matters yet to be resolved. Presently, the American Society of Hospital Pharmacists has set forth an accreditation standard for technician training programs.^{20,28} but some feel that this duty should fall instead to the American Council on Pharmaceutical Education.²⁹

In any event, the consensus opinion is that there should be a national standardized core of material for pharmacy technician training and certification.^{14,20,30} This core material would be supplemented with site specific information and procedural training.³⁰ The national certification would ensure that technicians pass a minimum competency requirement.

Many practitioners feel that the duties being performed by technicians should be determined by the supervising pharmacist on a site by site basis.²⁰ Also, many feel that licensure is unnecessary since the pharmacist, not the technician, is the autonomous practitioner, and should remain the person ultimately responsible for the technician's performance.^{12,18,20,29} This accountability system establishes a hierarchy where the pharmacist is the undisputed professional, and the technician is a member or the professional's support team. It also lets the pharmacist maintain control of site specific practice protocols and duty assignments.

Drug therapies today are more potent, specific and increasingly complex.^{1,10} The demographics of our society are changing. In the future a greater percentage of our population will be elderly; the largest group of medication consumers.¹ It is essential, therefore, that pharmacists become intimately involved in the clinical care of patients, as per the pharmaceutical care model. If support personnel are not utilized to their full potential, pharmacists will be unable to make the transition from drug dispensers to health care providers.^{15,17} This scenario would not only be detrimental to patient care, but would also mean that the profession of pharmacy was unable to attain the development goals set forth at the historic Hilton Head conference in 1985.

The profession of pharmacy must quickly resolve the issue of expanded duty technician use, so that pharmacists and technicians can work together to implement a cost effective, safe, and efficient version of the pharmaceutical care model.

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Methamphetamine Too Frequently

David B. Brushwood, R.Ph., J.D.



A Michigan appellate court has recently reinstated a \$3,800,000 award against a pharmacy (the award is to be reduced by half, based on the plaintiff's 50 percent comparative negligence). The trial court had granted judgment for the pharmacy, despite a jury award in favor of the plaintiff, but that court ruling negating the jury award was reversed on appeal.

The plaintiff visited a weight loss clinic, where he paid to obtain prescriptions for methamphetamine, ostensibly for weight loss. The plaintiff sometimes received a thirty-tablet prescription as often as three times per week. About 75 percent of these prescriptions were filled by the defendant pharmacy.

The plaintiff developed a mental illness, of which methamphetamine was a very important causative factor.

A pharmacy technician who worked for the defendant pharmacy testified at trial that she began to suspect that several of the customers of the pharmacy were drug addicts. She testified that the pharmacist did not attempt to verify that the customers were the people actually named on the prescriptions, and that the pharmacist would sometimes fill four or five methamphetamine prescriptions at once for a customer, with no record being kept as to how many times a customer would have a prescription filled. The technician testified that the pharmacist filled prescriptions for the plaintiff, and that some of the prescriptions filled were not in the plaintiff's name.

The pharmacy relied on a point of law that says no person may recover on a negligence claim for another person, if the person seeking recovery was involved in an illegal activity at the time of the other person's negligent conduct. However, the court noted that the pharmacy was also involved in illegal conduct, and one must have "clean hands" to invoke an equitable principle. Moreover, there was evidence that the plaintiff was mentally ill at the time he committed his illegal acts, and he may have lacked the capacity to resist performing the acts.

Judgment favoring the pharmacy was reversed, and the verdict against the pharmacy was reinstated. **R**

Based on: *Orzel v. Scott Drug Company*, No. 117270 (Mich. App 1993). Copyright 1994, David B. Brushwood. All Rights Reserved. Reprinted from *Dickinson's Pharmacy*, March, 1994

About the Author

David Brushwood is Professor of Pharmacy Health Care Administration at the University of Florida. His articles on cases affecting pharmacies and pharmacy are provided as a courtesy to state pharmacist associations. Questions on legal issues affecting Maryland practice should be directed to your legal representative or the Maryland State Board of Pharmacy.

Take Advantage of Tax Time

I.C. System, An MPhA-Endorsed Member Benefit Collections Program



If you didn't write your own policies for managing your accounts receivable, then who did? Are the people who owe you money deciding when and if you will be paid?

First, begin with the establishment of a definite policy regarding payment for services, the extension of credit and your billing cycles. The individual characteristics of your practice and competitive environment will affect your policy. You may consider everything from cash payments at the time of visits (in order to achieve a zero accounts receivable balance) to a liberal granting of terms to selected classes of patients. In particular, your policy should assign the responsibility for managing accounts receivable to only one person, and this person should report and be accountable directly to you (or your management team).

An example of a simple credit policy might be:

- All patients must complete a patient information sheet which calls for information related to the payment of amounts due as well as health issues.
- Delivery of health care to individuals on a credit basis must be given an explanation of payment schedules, dollar amount expectations and timely payment.
- Credit will not be extended to any patient whose accounts is 60 days past due.

Different accounting transactions present unique accounts receivable problems and some require more careful planning and control than others. For instance, a community pharmacist who regularly receives payments from insurance companies for one individual may have to institute one policy to handle insurance payments and timing, and another for payment of deductibles or directly billed patients. A long term care pharmacy might have a policy for nursing home residents and a separate policy for domiciliary care patients. The point is, different types of transactions require different handling and timing to maximize accounts receivable results.

Even with a payment and credit extension policy in place, you may not be the manager of your finances. Past due accounts are a fact of life for every practice. If you don't address this issue, you're letting your least profitable group of patients establish your policy for amounts which might equal or exceed your whole profitability profile.

Every health care organization or practice needs to establish a firm policy for handling past due accounts. Collection policies are as critical as credit policies.

A collection policy can be as simple as your credit policy. For instance:

- The Accounts Receivable Manager is responsible for all collection activity.

Concluded on page 30...

Take Advantage of Tax Time

Continued from page 29.

- An account becomes eligible for collection activity when it becomes 60 days past due.
- An account receiving collection activity will be pursued for 45 days.
- After 45 days, all unpaid accounts will be turned over to an outside professional collection agency.

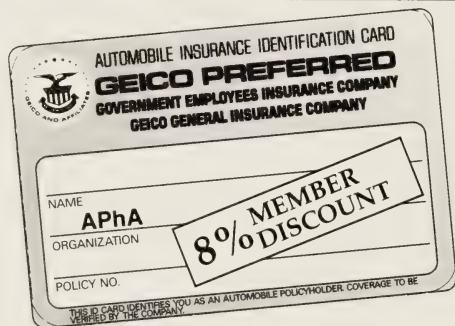
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Now is an ideal time for I.C. System to contact your debtors? Why? Because tax season is the time many debtors will be receiving tax returns. With a source of funds readily available to debtors, your collection agency may be able to settle many of your past-due accounts now.

I.C. System, MPhA's endorsed collection agency, recommends that you gather your overdue accounts and turn them over for collection as soon as possible in order to take advantage of this increased debtor cash flow.

Then, make it a practice to regularly turn in all accounts once they become 60 to 90 days delinquent. Waiting longer than that will lessen your chances of collection. And, there is little hope that your debtors will pay up on their own. According to the American Collectors Association, only five percent of accounts more than 90 days over-due will be paid voluntarily. Debtors who have let their past-due bills go this long without payment often need an extra push from a collection service to pay up.

If you need to take a new look at who's managing your finances and could use some help, call I.C. System, our recommended collection service, at (800) 325-6884.



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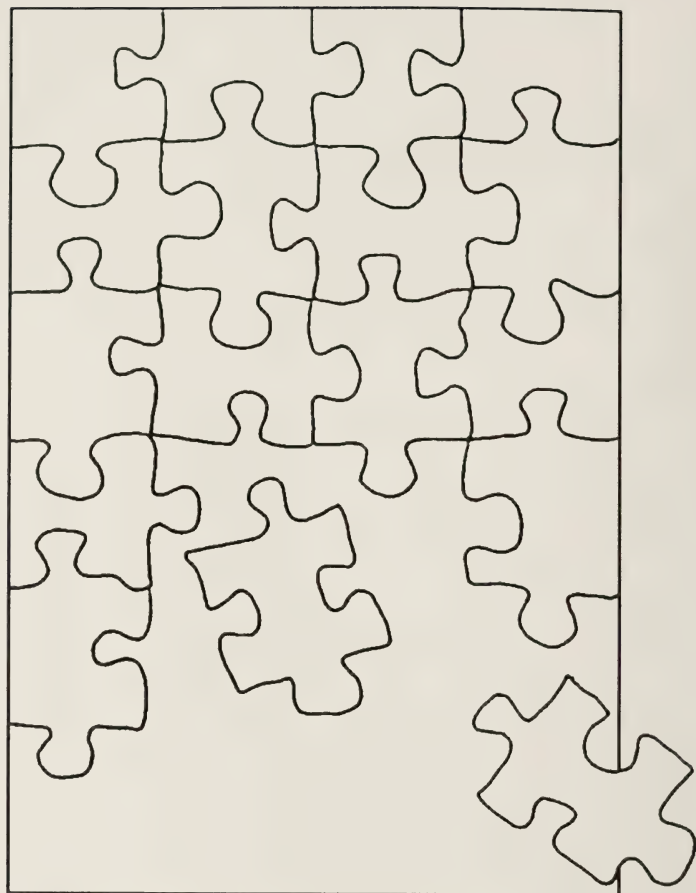
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*Maryland Pharmacy Loses
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**The pieces
fall together
in just
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months
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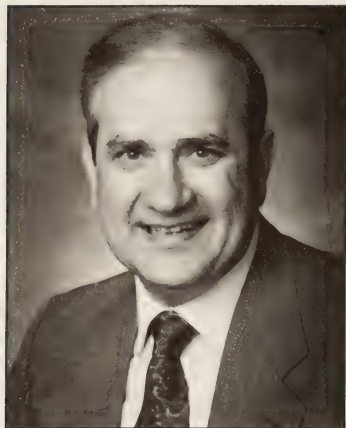
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President's Commentary

Howard Schiff, P.D.



Maryland's pharmacy community was dealt a cruel double blow in the past few weeks as Death claimed both Dr. Peter Lamy and MPhA's former Executive Director David Banta. In my opinion, their careers underscore the changes that have come to pharmacy in Maryland over the last 20 years.

Peter Lamy graduated pharmacy school the same year I did. I went to Maryland at the time when it was not considered to be the elite school it is today. Peter came to us in 1963 and, at the time of his death, had brought world renown to himself, his school, and the pharmacists in Maryland. He was a winner of pharmacy's most prestigious awards, a man whose work changed the treatment of the elderly.

Dave Banta came to MPhA when it was in need of new leadership. He gave professional guidance and bridged the gap to the modern era of practice - the time of third parties and outlandishly expensive medications. He laid the groundwork for MPhA to become one of the top associations in the country.

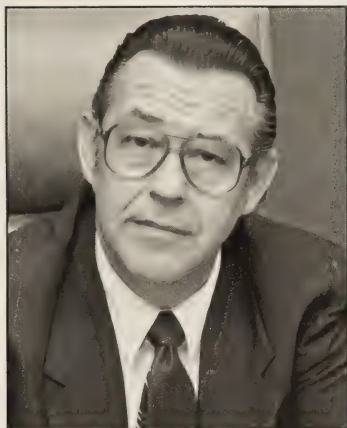
Dr. Lamy will be greatly missed. He was at the top of his life's work and could only have gotten better. It should have been his time to bask in the glory of it. Dave Banta had already moved on to bigger and better things -- a young man still not having reached his peak. It's a shame anyway you look at it.

This issue of *The Maryland Pharmacist* includes two memorial articles that highlight the careers of our colleagues. It seems a small gesture when compared to their contributions. If you feel compelled to help recognize their support of Maryland pharmacy, I encourage you to donate to the two memorial funds that have been designated by their families. A Lamy Memorial Fund has been established at the University of Maryland School of Pharmacy, 20 North Pine Street, Baltimore, Maryland 21201. David's family, recognizing his excitement over his new position has asked that donations be sent to the American Sunbathing Association's Legal Fund, 1703 North Main Street, Suite E, Kissimmee, Florida, 34774.

The Elderly: Challenge and Opportunity

Remington Award Lecture

Peter P. Lamy, Ph.D., Sc.D., Remington Medalist, 1988



The 1988 Remington Medal was presented on March 12, 1988, in Atlanta, Georgia, at the opening session of the American Pharmaceutical Association annual meeting March 12-16, 1988, held in the Georgia World Congress Center. Lamy's remarks were not published, but a transcript has been prepared from a tape recording and from Lamy's recollection. This lecture and the biography of Dr. Lamy were taken from APhA's publication, The Remington Lectures: A Century in American Pharmacy compiled and edited by George Griffenhagen.

It is a pleasure to accept this award, the highest in American pharmacy. I accept it with great pleasure, as it gives me an opportunity to recognize those who have made this possible and those who have helped me throughout my career. I want to extend my appreciation to my peers who voted me recipient of this medal. Let me express my special thanks to my family, my wife Angela, my daughter Margaret Luise, my son Rudolf, and my son Carl, all of whom, incidentally, worked very hard helping me with my book [*Prescribing for the Elderly*] and all of whom have supported me throughout these last four decades. Let me also introduce my son-in-law, James Lachowicz, a Lieutenant Commander in the U.S. Coast Guard. It heightens my appreciation and pleasure to receive this medal in their presence.

Of the many colleagues who have helped me and supported me in my goals, three stand out, three who made it possible for me to receive this valued award. They spearheaded the effort, they were the driving force. They are Mrs. Madeline Feinberg, director Elder Health Program, of the University of Maryland; David Banta, executive director of the Maryland Pharmacists Association, and Dr. Philip Gerbino, professor at the Philadelphia College of Pharmacy and Science and director of the Philadelphia Geriatric Institute.

It is most important for me to extend my appreciation and thanks to Parke-Davis for supporting my efforts and my Center.

Specifically, I would like to recognize Joseph Dilger of Parke Davis and Walter Weglein from Warner Lambert for their unstinting support. Of course, there are many others from the School of Pharmacy, University of Maryland and the Philadelphia College of Pharmacy and Science and many organizations who, over the years, have helped me to pursue my interest in the elderly and their needs.

I like the elderly. Why do I like them? I like the elderly because they are nice group of people, often with a wonderful sense of humor. Recently, President Reagan said, "Finally, I am on a national network, and I want to say something." Well, today, I want to say something about the elderly who represent a challenge and an opportunity to pharmacy and pharmacists.

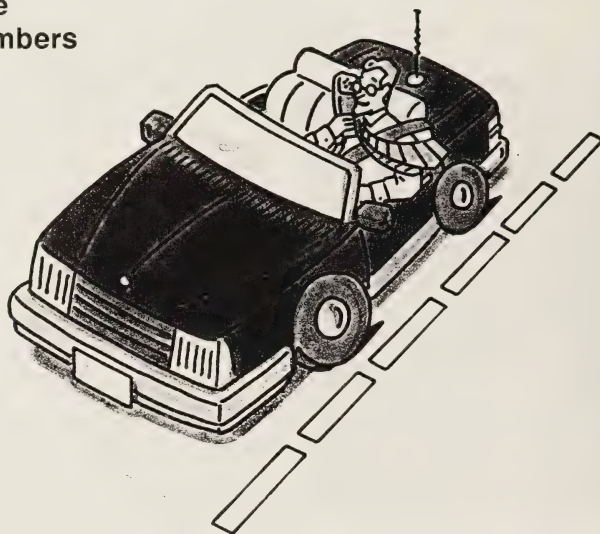
The elderly, often with multiple diseases receiving multiple drugs, need help. The National Institute on Aging has called for an interdisciplinary community-based system for the care of the elderly, in which we, as pharmacists and drug experts, must participate. We have not yet achieved in helping to set up that system and participating in it.

Let us look at what others are doing. The internists have gotten together and asked "are we doing the right thing"? Are we teaching our students so that they can practice 30-years hence? And what type of practice will there be 30 years from now? It is not going to be institutional practice. It is going to be ambulatory practice without the humongous backdrop that we have in the hospital. It is going to include information centers using the latest in high technology. We need to teach our students that, and we haven't done it yet.

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When I first went to work with Peter Lamy, nearly 15 years ago, I remember him saying how much he enjoyed working with the elderly.... because they called him "young man." Indeed, 15 years have passed and I can now certainly appreciate his perspective! It was a tremendous experience working with Dr. Lamy. He had an enormous knowledge, but it was special, because it was combined with understanding and intuition that enabled him to interpret information and put it into a perspective that was unique. And it wasn't confined to just geriatrics. He recently showed me a publication he had written, way back in the very early 1980's, when he described the concepts of pharmaceutical care. He was impatient that it took so long for new ideas to catch on. But when an idea caught on, he loved it! Nothing gave him as much pleasure as a practitioner or a student who grabbed an idea, put a spin on it, and ran with it. "Hey," he would say, "that's great!" The most important thing to Peter Lamy, and he always said this to his students, is that no matter what you do, it must be fun. Geriatrics was fun for Peter. Because he loved a challenge.

*Madeline Feinberg, Pharm.D.
Director, Elder Health Program*

reported that unfortunately physicians do not participate in home care, and this year they tell us that we are doing a poor job in practicing for the elderly. Why are we not pushing the federal government to provide pharmacy with the same kind of federal support which is available to psychologists, psychiatrists, physicians, dentists, and nurses?

In December 1986, there was a meeting in Baltimore co-sponsored by pharmacy and the National Institute on Aging to evaluate clinical pharmacy and geriatrics. The conclusion was that the teaching of physicians is often accomplished by pharmacists, but we do not have support to teach a clinical pharmacist. Instead the federal government turns to regulations. Starting in 1990, there must be an outside expert for every nursing home who checks to see if I am using psychotherapeutic agents correctly.

What can (and must) Pharmacy do? Let's look at the changes in the health care system. The old and traditional boundaries of pharmacy are changing. There is no longer a clear delineation between community

pharmacy, chain store pharmacy, and hospital pharmacy. These boundaries are blurring and disappearing. The site of care is changing, based on patient demands and cost considerations. We now deal with preventive care, acute care, and chronic care. Seventy percent of all prescriptions dispensed are chronic care drugs, to be used not only in nursing homes, the "traditional" site of long-term care, but to the six million elderly in home care and the three-quarter of a million elderly in assisted care. We need to develop systems of outcome-oriented pharmacy care for these care sites.

And if we are too slow, we will, no doubt, be told what to do. Last October, the Federal Register published new regulations under the heading of OBRA 1987. Under these regulations, pharmacists will be held responsible to monitor psychotropic drug use, especially antipsychotropic drug use in nursing homes and the use of unnecessary drugs. We will need to monitor that it not only is the right time, but that it is the right drug prescribed for a specific diagnosis and with a therapeutic outcome specified. We will need to monitor whether the outcome is reached.

Thus, we will need pharmacists well-trained in these concepts and care procedures. We will need to have schools of pharmacy adjust their curricula, and we need to convince our pharmaceutical organizations to keep convincing legislators and insurers that pharmacists are, indeed, the drug experts badly needed in the care of elderly.

In any case, I appreciate the high honor. To those of us who were welcomed to this country with open arms, it is nice to be able to give something back. For this I thank all of you. **R**

Dr. Peter Lamy's contribution to pharmacy, as well as to the elderly, is immeasurable. Although my association with him was somewhat limited, I was impressed by his honesty and openness, his humor and his willingness to provide his assistance to anyone who requested it. Most of all, I was impressed by his deep rooted commitment to his profession and to those beliefs he so freely espoused. Pharmacy in Maryland will never be the same without him and he will be sorely missed by all who knew him. I am certain that God is making use of Dr. Lamy's talents in the hereafter.

*Murhl L. Flowers, P.D.
Pharmacy Director, Safeway, Inc.*

A Year of Progress

David A. Banta, C.A.E., Former Executive Director, Maryland Pharmacists Association



This presentation by former MPhA Executive Director David Banta was first published in the July 1980 issue of The Maryland Pharmacist, only a few years after he joined the organization. We have selected this sample of his writing to show the optimism and dedication he had to our organization. His words of then are just as true and applicable today.

I am very pleased to give the Annual Report of the Executive Director of the Maryland Pharmaceutical Association. This past year has truly been one of accomplishment and challenge. Yet, challenges are simply unmet opportunities for us to further improve the profession through our Association.

Since I allow myself only one speech per year to the membership concerning my perspective of the Association, I will attempt to execute it with a maximum of brevity and a minimum of rhetoric without becoming too nostalgic in the process.

If you have reviewed the Committee reports that have been distributed to you, I think one thing must become forcefully obvious. This Association, in spite of crippling national inflation and the trend to apathy, is not only growing, it is prospering and becoming stronger with each passing year.

This growth itself, in terms of membership and financial resources, offers a challenge to us. Are we capable of adjusting from the status quo? Can we manage the transition to a capable, aggressive and responsive organization to meet the needs of the members in new and innovative ways? I think that answer is pretty obvious, or we would not have come as far as we have to date.

There is a lot of favorable chemistry in this state. That may sound a little strange, but let me explain. Maryland is blessed with a unique combination of factors which allow pharmacy here the environment necessary to advance in progressive ways.

Maryland is a unique mixture of urban and rural geography and various professional practice settings that include retail, hospital, government, research, education and more. There is something about Maryland pharmacy that informs the outsider that important things are possible in this environment. Maryland was, after all, the first state to pass the model drug product selection law. We have one of the finest schools of pharmacy in the nation. Even our advances on the third-party front have made national news. Our Board of Pharmacy is growing stronger each year and the models for cooperation between our various state organizations are the envy of other states.

I can sum all of this up by saying that I am proud of the past and optimistic for the future.

Such optimism, however, brings with it a certain sense of liability. Performing this job as I have over the last three years, I am constantly aware of the fragile nature of our success. The bottom line is that no Association can be successful without the involvement of its membership. Membership involvement is another constant challenge we must continue to meet successfully. We have accomplished what we have because of the dedication and hard work of a number of individuals who give of themselves and their time with little recognition. I am speaking of the officers, trustees, committee chairmen and the MPhA committee members. I am speaking of the individual members who volunteer to handle tasks for the Association. We are blessed with a number of these individuals and they are the cornerstone of whatever success we may enjoy.

Obituary

David Alan Banta, age 46 of 1156 Yardley Court, Kissimmee, Florida, died Sunday, April 10, 1994 at Osceola Regional Hospital in Kissimmee as a result of injuries sustained in an automobile accident.

Born August 19, 1947 in Lafayette, Indiana, Banta was a 1969 graduate of Ohio State University. After serving two years as an Army officer, he earned a master's degree in journalism and public relations at Ball State University in Muncie, Indiana in 1973. David was a Certified Association Executive of the American Society of Association Executives.

Beginning with a position of assistant executive director of the Indiana Pharmacists Association, David's career became inextricably linked to the pharmacy profession. From 1977 until 1988, he was executive director of the Maryland Pharmacists Association and the Baltimore Metropolitan Pharmaceutical Association. He also taught at the University of Maryland pharmacy school.

After leaving MPhA, Banta was deputy executive vice president of the American College of Health Care Administrators and director of pharmacy relations for Blue Cross and Blue Shield of Maryland. From 1991 until recently, he was regional director of governmental affairs for the Pharmaceutical Manufacturers Association.

David had just accepted a new position as executive director of the 40,000 members American Sunbathing Association in Florida. He was in the process of moving into a new house when the car he was driving collided with a truck.

He is survived by his wife Robin Platts; two sons, Scott and Matthew; his parents, Joseph and Phyllis Banta of Brooksville, FL; a brother and a sister.

Yet the challenges we face as an organization are formidable. There are still more non-members than members in the MPhA. We must continue to build the Association's reserves, while improving benefits and services to the members. We must increase our lobbying efforts and the involvement of pharmacists in the political process. We must continue our fight for the economic viability of community pharmacy practice. We must work to expand the scope of care that pharmacists can provide to the public while being reimbursed for that increased service. And we must

plan for our future so that we control our own professional destinies. Too often pharmacy has reacted to negative changes, rather than working to create positive changes.

I know we can accomplish these goals and more. Next year's report, I know, will reflect again the growing strength and growing pains of the Association. It has been a pleasure for me to work for you over the past year. Let us continue together to work for pharmacy's future and face the challenges through a strong Maryland Pharmaceutical Association. R

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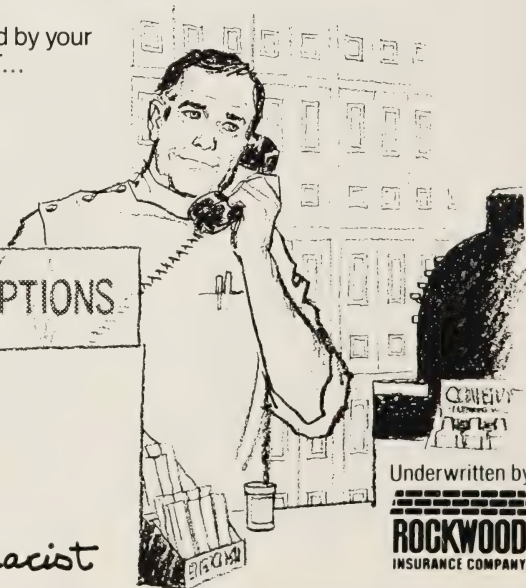
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The Report From Annapolis

A Wrap-Up of the 1994 Legislative Session

Robin F. Shaivitz, Legislative Consultant, Maryland Pharmacists Association



What a hectic session this truly was. On top of the usual difficult issues and intense lobbying efforts required of all MPhA members to advance the profession's legislative agenda, we were facing the ups and downs of an election year and a reassigning of many of our bills to the House Economic Matters rather than the usual Environmental Matters. However, one of the best benefits of this session was not the success or failure of a particular bill, but instead the forging of a new health care provider coalition in which pharmacists play a major part.

I have chosen several bills to highlight for you. While the Association followed many, many more than just these issues, I believe that these warrant special attention as they can give you an insight into the nature of the political game that pharmacy and pharmacists must inevitably play. In addition, a complete listing of the bills that the Maryland Pharmacists Association tracked accompanies this article. I encourage each of you to review these bills because they give a more than adequate picture involvement of your professional organization.

House Bill 194

**Labeling of
Generically
Equivalent Drug
Products** This
bill was
introduced by
Delegate Braun

of Calvert County and heard in his committee, Environmental Matters. A constituent of his had a problem when the doctor mentioned the name

brand of a drug he was going to prescribe for the patient and when the patient received a generic equivalent. Because the names were different, the patient did not know what the generic drug was for. House Bill 194 required pharmacists to inform patients about both the brand and generic names whenever a generic was dispensed. We worked long and hard with Delegate Braun to come up with an alternative solution since identifying the generic with the name brand may not be legal nor necessarily correct. We also explained to the Delegate that these changes would require major and costly computer software and hardware changeovers. We did agree to pursue a voluntary solution to this problem and you will be hearing more from the Maryland Pharmacists Association on this issue.

House Bill 262

Prescription Forgeries and Penalties

For three years,
M P H A has
worked to
increase the

penalty for forging or attempting to pass a forged prescription from a misdemeanor to a felony offense.

Thanks to some wonderful work by the bill's sponsor, Delegate Preis, it finally passed the House and moved cautiously to the Senate. The bill provides that a person who knowingly possesses, passes, utters, makes, or manufactures a false, forged, or altered prescription for a controlled dangerous substance is guilty of a felony. The bill moved to the

daunting Senate Judicial Proceedings Committee where it did not receive a vote until *the very last day* of the session. The vote was favorable and the bill was rushed onto the Senate floor where it finally, after three sessions, passed.

House Bill 330

Health Insurance Reform -- Clarifications and Modifications

Subsequent to the passing of Maryland's health care reform initiative in 1993, it became apparent that the legislation required several amendments and corrections. While intended to be only for "technical" amendments, House Bill 330 became the vehicle for many more changes. This tinkering became serious enough that members of the House Economic Matters Committee reprimanded the staff of the Health Care Access and Cost Commission for lobbying and going too far with their amendments.

The only effect to pharmacy from this bill was the inclusion of pharmacists in the annual health care provider assessment to pay for the Health Care Access and Cost Commission and its legislatively mandated services. While pharmacy had previously been exempt, we knew that this oversight would not last for long.

HB 346 and SB 32

Confidentiality of Prescription Records

A n M P h A initiative for this session was the passage of legislation to protect the confidentiality of prescription files and records. MPPhA discovered through research that under previous Maryland law, pharmacy files and records were *not* protected by Maryland's confidential medical records act. These bills correct this oversight. As pharmacist expand their pharmaceutical care services, we

believed that protection of our records and documentation was essential to expanding our role as primary health care providers.

House Bill 439

HMOs and 24-Hour Telephone Assistance

This bill was introduced by Delegate Weir of Baltimore County to address a perceived lapse in the quality and continuity of care given by HMOs. This bill originally required HMOs to have a 24-hour hotline staffed by HMO employees to receive calls from members about medical emergencies. The bill moved to Senate Finance where it was watered down and finally passed with language that says the HMOs need only have someone (anyone) available to answer the phone. Every pharmacist who has had an HMO claim denied because of eligibility questions on a Sunday evening knows how essential it is to have an HMO staff person available to answer questions. MPPhA supported the bill.

HB 516 and SB 563

Triplicate Prescriptions

Once again, MPPhA and others fought triplicate prescription blanks and, this year, added to that colored-serial numbered prescription blanks. Each of these bills turned pharmacists into data collectors for the State; however, none of the legislation would have required any action to reduce diversion. These bills were all voted down in their respective committees after a great deal of education on our part as to why this is unnecessary for pharmacy.

House Bill 522

Discriminatory Pricing

This bill was introduced by pharmacist and Delegate Donald Elliott and was

strongly supported by many other delegates, including the pharmacist/Delegate Bennett Bozman and pharmacist/Delegate Ted Sophocleus. This bill if passed would have required both manufacturers and wholesalers to offer the same purchase terms and discounts to all purchasers with the consumer winning in the end from lowered overall prices.

MPPhA worked closely with the Maryland Association of Chain Drug Stores and the National Wholesale Druggists Association to craft and tighten the language contained in the bill. Unfortunately, while there was great interest in the issue, the Economic Matters Committee narrowly defeated the bill.

HB 691 and SB 472

Patient Access Act

Or as we as Pharmacists have known it, "freedom of choice," was among the hottest issues in the legislature this year. In years past, MPPhA had gone after open access to HMO and insurance company benefit networks alone. All the legislators repeatedly remarked that if this issue is so important, why aren't any of the other health professionals concerned?

Last year the Chairman of Environmental Matters would not even allow his Committee to vote on the bill because we were able to gather so much support from his Committee. He saw the potential of a pharmacy "freedom of choice" bill as opening the proverbial Pandora's Box for the rest of Maryland's health care providers. Since we weren't able to get what we wanted by ourselves, we decided that this year, we would just make everyone's worst fears come

true.

We have developed a cohesive and strong coalition of health care providers. Together we worked hard and well to fight for patient access or as the opposition likes to call it, "any willing provider." The opposition threw every curve possible. The behind-the-scenes political machinations read like a legislative soap opera. Here's a rundown of what happened.....

The House Committee voting on HB 691 was Economic Matters - Speaker Casper Taylor's former committee. Although we made headway with many committee members including Delegate Hurson, that committee's Sub-Committee Chairman of Health Care, strong messages from the House leadership indicated that the bill was to die. Recognizing a road block, the provider coalition then tried to amend the "freedom of choice" provisions onto another health care bill. When the Speaker saw we were making even more progress with this

approach, he along with President of the Senate Mike Miller and Health Secretary Nelson Sabatini called a press conference and announced that our bill would be killed in the House and Senate and the matter would be looked into by a special task force made up of insurance and government representatives. Of course, we were concerned that the make-up of this "task force" would be all pro-insurance and anti-health care provider.

The Senate Finance Committee was then told they could not vote on their version of the patient access bill (Senate Bill 472) after this press conference. The Committee was furious with both the President and their Committee chair who had promised them a vote. To paraphrase their words, they were sent to Annapolis to be able to vote and help their constituents, not to acquiesce to the wishes and whims of the leadership. (At the same time Senator Finance Committee Chairman O'Reilly announced his

resignation effective just after the session.)

Amendments were attached to the Senate version of the bill that would allow HMO patients to use out of network providers and pay 25 percent and the HMO to pay the remaining 75 percent of the reimbursement rate they normally pay to their participating network providers. The coalition recognized that while this was not the perfect solution, some patients would opt for this every time, some occasionally, some never. Meanwhile, the Finance Committee was furious that the Chair had reneged on his promise to vote and, in a very seldom performed action, signed a 6 member petition to force the Chair to vote on the bill. Senate Bill 472 then passed the Finance Committee 9 to 2 -- but several members of the committee surprised everyone with amendments to the bill.

The next round of fighting was when the bill got to the full Senate for a vote. Our opposition employed



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a number of delaying tactics including a special order resulting in three days of delays, a lay over, and an unsuccessful attempt at several amendments on the Senate floor. Unfortunately, the delaying tactics worked and the bill died on the Senate floor before coming up for a final vote.

Our obstacles on this were truly insurmountable - House and Senate, leadership, the Governor and Health Secretary, Labor, the Chamber of Commerce, the entire insurance industry and HMOs, and all the large utility companies (including Baltimore Gas and Electric and Bell-Atlantic). The final enemy was the clock. As one Senator said to one of our opponents, "the clock always wins."

House Bill 1527

Physician Assistant Prescribing

This bill began over the summer with a House Environmental

Matters summer study work group. We testified before that group and worked closely with the chairman, Delegate Virginia Thomas. A bill was drafted, that limited to physician assistants to prescribing within inpatient hospital settings, where P.A.'s could prescribe. MPhA supported the bill when it was introduced with the language that had been part of the work group's final recommendations.

When the physician assistants testified at the bill's hearing during the session they wanted to broaden the bill's parameters so that it applied to several -- if not all practice settings. After heavy lobbying by the physician assistants, the bill was passed by the House Environmental Matters Committee with very liberal language. Suddenly we, along with the medical society, the chain drug store association, the nurses, dentists, and other health care providers, were all concerned about this ramifications of this bill. Working together we were able to kill the bill on the House

floor, undeniably a formidable task! However, as one delegate wisely pointed out, "If we don't let paralegals practice law in this state, why would we let physician assistants practice medicine?"

HB 1222 and SB 754

Off-Label Uses of Drugs

When new but non-FDA approved uses for previously approved drugs are discovered, doctors can prescribe for these uses. However, some insurers and HMOs have decided to deny reimbursement or coverage for off-label uses of approved products. This bill now prohibits this practice complaints or denials of coverage. House Bill 1222 passed in close to its original form. The Senate companion bill (SB 754), however, was one of the bills amended at the last minute as a vehicle for patient access language. It was defeated.

Senate Bill 599

Home Infusion Providers Licensing

This bill would have required home infusion pharmacies to obtain an *additional* license from the Department of Health and Mental Hygiene and to abide by additional regulations. MPhA opposed this legislation because the Board of Pharmacy already has regulations governing home infusion pharmacy practice and because we philosophically do not believe that any pharmacy should have to pay for an additional license when a license or permit is already been given.

We were successful in defeating this bill in the Senate Finance Committee.

House Bill 1601

Freedom of Choice for Medical Assistance Recipients

Introduced by a coalition of chain

drug stores and with help from the Maryland Pharmacists Association, this bill was designed to address the patient access rights of Medical Assistance recipients who are enrolled in HMOs. In some instances, Medicaid subscribers in HMOs are not allowed the same choice of network providers as other non-Medicaid HMO subscribers. We believed this to be a clear-cut case of discrimination.

We were unable to pressure that Chairman of Environmental Matters to even allow his committee to vote on the bill. We tried to attach these same provisions onto several other bills to keep the concept alive. The bill did not pass.

Editor's Note: The following pages list the major legislative issues monitored by the Maryland Pharmacists Association's Legislative Committee. In addition to those bills featured in this article as well as in the bill charts, MPhA was involved in many more issues that impacted on pharmacists and the profession.

1994 Legislation Affecting Pharmacy

Bills Introduced in the Maryland Senate

Bill	Title	Sponsor	Description	MPhA Position	Status
Senate Bill 32	Medical Records - Prescription Orders	Hollinger	Clarifies in statute that prescriptions are medical records and that the confidentiality of medical records statutes apply to pharmacists.	Support	Passed
Senate Bill 75	CDS - Marijuana - Penalties	Haines	Reduces from 100 to 10 the number of pounds that it is unlawful to possess in Maryland.	Monitor Only	Killed
Senate Bill 127	CDS - Nitrous Oxide	Departmental	Makes it a misdemeanor to inhale or illegally distribute nitrous oxide for the purposes of intoxication.	Monitor Only	Killed
Senate Bill 261	HMO's - Contracts with Providers	Young, Trotter	Prohibits HMO's from excluding providers because of race or sex of the provider.	Support	Withdrawn
Senate Bill 304	Death by Lethal Injection	Administration	Provides for change in execution method to lethal injection. Bill allows pharmacist to dispense necessary chemicals to Commissioner of Corrections without a prescription.	Monitor Only	Killed (other version passed)
Senate Bill 472	Health Care Patient Access Act	Levitan, Baker, Hollinger	Senate companion bill to HB 691.	Support	Killed
Senate Bill 482	Home Medical Equipment Providers	Young, Sher, Wagner	Requires home medical equipment providers to be licensed by the Department. Provides for regulations to be established by the Department.	Amend Pharmacy Out of Bill	Passed
Senate Bill 509	Home IV Drug Therapy Services	Garrott	Establishes a lengthy series of provisions for home IV providers in the pharmacy law. Also provides for provider reimbursement under Medicaid.	Support and Amend	Killed
Senate Bill 563	Triplicate Prescriptions	Lapides, et.al.	Provides for triplicate prescriptions for all Schedule II's.	Oppose	Killed
Senate Bill 599	Health Care - Home Infusion Providers	Bromwell, et.al.	Requires home infusion providers to be licensed and regulated by the Department outside the Board of Pharmacy's existing oversight.	Opposed	Killed

Bill	Title	Sponsor	Description	MPhA Position	Status
Senate Bill 635	Insurers and HMOs - Access to Records	Levitan	Prevents and HMO or insurer from going back more than 1 year to collect overpayments from providers.	Support	Killed
Senate Bill 741	HMO's - Contracts - Requirements	Young	Creates standards for HMO's to use in contracting with providers. Provides for specific termination and hearing rights.	Support	Withdrawn
Senate Bill 754	Health Insurance - Coverage for Off-Label Uses of Drugs	Sher, Young, Lawlah	Prohibits insurers from denying coverage of drugs because the use is not FDA approved. Establishes a board to review drugs.	Support and Amend	Killed
Senate Bill 783	HMO's - Pharmaceutical Services	Piccinini	Prohibits HMOs from requiring multiple copayments on maintenance prescriptions.	Support and Amend	Killed

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1994 Legislation Affecting Pharmacy

Bills Introduced in the Maryland House

Bill	Title	Sponsor	Description	MPhA Position	Status
House Bill 38	Retail Establishments - Security for Employees	Kelly	Requires that any retailer open between 11:00 pm and 7:00 am must have two employees on duty and security cameras.	Oppose	Killed
House Bill 85	Health Insurance - Provider Service Arrangements	Alexander	Requires all insurers, HMOs to accept "any willing provider" who wishes to participate in their benefit networks. Includes pharmacy.	Support	Withdrawn and Changed to HB 691
House Bill 193	Retail Pharmaceutical Products - Preferred Provider Rates	Braun	Requires a pharmacy to extend "preferred provider rates" to patients regardless of their residence.	Oppose	Withdrawn
House Bill 194	Pharmacists - Substitution of Generic Products	Braun	Requires pharmacist to provide written notice of what a generic substitute is equivalent to.	Support and Amend	Killed
House Bill 262	Prescriptions - Forgery - Penalties	Preis	Similar bill to HB 123. Would make forging a prescription a felony.	Support	Passed
House Bill 330	Health Insurance Reform	Department	Extensive corrections to MD's health reform act of 1993 (HB 1359). Bill does eliminate pharmacy's exclusion from paying an annual assessment to the HCACC.	Oppose Pharmacy's Inclusion in Fee Collection	Passed
House Bill 346	Confidentiality - Prescription Records	Thomas	Companion bill to SB 32. Provides that prescriptions are confidential medical records.	Support	Passed
House Bill 371	Workers Compensation - Timely Payments	Workman	Provides that a penalty may be assessed if an employer or its insurer fails to pay a submitted provider claim within 45 days.	Support	Killed
House Bill 439	HMO's - 24 hour Emergency Services	Weir, Maddox	Requires HMOs to have a 24 hour staff person available to help members with emergency services	Support	Passed
House Bill 452	CDS - Schedule Change - Alphacetylmethadol	Bozman, Elliott, Sophocleus, et al.	Moves alphacetylmethadol from Schedule I to Schedule II.	Monitor Only	Passed

Bill	Title	Sponsor	Description	MPhA Position	Status
House Bill 516	CDS - Triplicate Rx Blanks	Fulton	Requires trip scrips for all CDS prescriptions. Requires distributors and manufacturers to report and pay an annual fee to supplement costs of monitoring system.	Oppose	Killed
House Bill 522	Commercial Law - Drug Pricing	Elliott, et al.	Prohibits manufacturers and wholesalers from having multi-tier pricing. Provides treble damages as penalty.	Support	Killed
House Bill 691	Patient Access Act	Alexander	Requires open access to all HMO and insurance networks to providers willing to participate.	Support	Killed
House Bill 849	Health Insurance - Medication Management	Thomas	A new mandated benefit that would provide for medication management as a covered service under mental illness treatment services.	Support	Killed
House Bill 876	CDS - Colored Prescription Blanks	Sophocleus, Astle, Elliott, Bozman, et. al.	Requires authorized providers to use only a colored, counterfeit-proof prescription for all C-IIs.	Support and Amend	Killed
House Bill 894	Sales Below Cost - Repeal	Kittleman	Repeals sales below cost act.	Oppose	Killed
House Bill 1010	Prescriptions - CDS - Serialized Blanks	Astle, Sophocleus	Requires authorized providers to use only a serialized counterfeit proof prescription for all C-IIs. Requires pharmacists to provide a copy to the Department.	Oppose	Killed
House Bill 1222	Health Insurance - Coverage for Off-Label Uses of Drugs	Marriott, Exum, et. al.	House companion bill to SB 754.	Support and Amend	Passed
House Bill 1292	HMOs - Contracts with Providers	Jefferies, Cummings, Kirk	House companion bill to SB 261	Support	Withdrawn
House Bill 1527	Physician Assistant Prescribing	Thomas, et. al.	Permits prescribing of PA's in hospitals only with supervision and oversight by physicians.	Support with Board Rx Amends	Killed
House Bill 1601	MA Recipients - Pharmaceutical Services	Sophocleus, Bozman, Kelley	Requires managed care/HMO enrolled Medical Assistance recipients to allow all pharmacies to participate and to allow all patients the right to choose their pharmacy.	Support	Killed

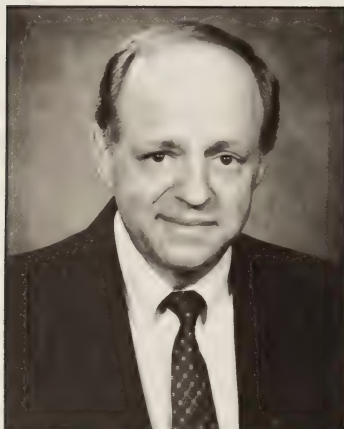
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Advising Patients on "Switch" Drug Products

Part III: Counseling on Topical Drugs Switched from Prescription

Thomas A. Gossell, R.Ph., Ph.D., Dean, Ohio Northern University

J. Richard Wuest, R.Ph., Pharm.D., Professor of Pharmacy, University of Cincinnati



The following information is offered as a guide to patient counseling on topical drugs switched from prescription to OTC status. Each monograph is presented separately as a self-standing review of important information to present to individuals selecting these drugs for self-medication. Table 1 lists representative topical drugs that have been shifted from prescription to OTC status.

The Future of the Rx-to-OTC Switch Movement

While it is difficult to predict the future accurately, nearly every article on the OTC switch issue states that there will be a surge of current prescription-only drugs being brought to the OTC market.

If this occurs, it will not be through the review-monograph process. While there are a few drugs pending in this system, most potential candidates for switching either were not part of the review, or have come on the market after the panels completed their work.

Another reason is the distinct advantages that the New Drug Application (NDA) process affords manufacturers. Since 1984, holders of NDAs can obtain up to the OTC market. This is a tremendous incentive to the NDA holder whose prescription drug is nearing expiration of its patent. By proving to the satisfaction of FDA that the drug is safe for self-medication, the manufacturer has several years to convince the public of the worthiness

of its brand of product. After that, competition becomes a problem.

In recent years, prescription drugs going off patent have lost their exclusive market share quickly. Often times this drops to less than 20 percent in a few years. Therefore, economics and corporate viability will play a major role in the Rx-to-OTC switch future.

Drugs that have been suggested as candidates for switch from prescription to OTC status may be perceived as dangerous. These feelings may be based on personal perceptions that here are dangers and safety questions associated with the drugs listed in Table 2. Some may seem bizarre, some may appear as wishful thinking, and still others may be perceived as dangerous. These feelings may be based on personal perceptions that there are dangers and safety questions associated with the drugs listed.

Nonetheless, change and progress come about when old biases and prejudices are discarded. Many of the drugs listed are currently available without prescription in countries other than the United States with no apparent negative impact on the citizens of those countries.

As a point of reference, Table 3 lists drugs that are prescription only in the United States, but available without prescription in Canada, Great Britain and/or Australia. The Scandinavian countries and Germany have many more drugs available without prescription. The same could happen here.



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Summary

The OTC Drug product marketplace is constantly changing. One viable component is the increasing number of OTC products that formerly required a prescription for purchase. This number is significant, and still increasing. Most new OTC drug ingredients of the future will undoubtedly originate from within the prescription drug product category. Pharmacists who let the public know that they are willing and able to counsel them on self-medication product selection can help lessen the resulting loss of revenue to non-pharmacy outlets, and raise their own status in the community.

General Information

1. Read all of the labels on the package before using this product. If you have any questions regarding this medicine, ask your pharmacist or doctor.
2. Use only as directed. Do *not* use more often than recommended on the product's label.
3. While any medicine can cause side effects, most people experience few or none. However, if the medicine is bothering you and causing unusual reactions, call your doctor or pharmacist.
4. Be sure to tell your pharmacist about allergies you have to any medicine before selecting over-the-counter products.
5. Call your doctor if you develop a skin rash, hives or itching, swelling of the face or difficulty in breathing while using this medicine. These are signs of an allergic reaction.
6. Store your medicines out of the reach of children.
7. Do *not* use or keep outdated medicines. The expiration date should be printed on the package by the manufacturer.

Representative Topical Drugs Shifted From Rx to OTC Status*

Ingredient (Shifted by)**	Dose (Adult)	Indication	Example
Clotrimazole (NDA)	Topical 1%	Antifungal	Lotrimin AF
Clotrimazole (NDC)	Vaginal 1%	Antifungal	Lotrimin & Mycelex
Dyclonine (Panel)	Vaginal 100mg		Sucrerts
Hydrocortisone (Panel)	Lozenge 3mg	Anesthetic	Cortaid
Miconazole (Panel)	Topical 0.5-1%	Antipruritic	MicaTin
Miconazole (Panel)	Topical 2%	Antifungal	Monistat 7
	Vaginal 2%		
	Vaginal 100mg		
Oxymetazoline (Panel)	Nasal 0.05%	Decongestant	Afrin
Oxymetazoline (NDA)	Eye 0.025%	Decongestant	Ocuclear
Permethrin (NDA)	Topical 1%	Pediculicide	Nix
Sodium Fluoride (Panel)	Rinse 0.05%	Dental Rinse	ACT
Stannous Fluoride (Panel)	Gel 0.4%	Dental Rinse	Gel-Tin
Stannous Fluoride (Panel)	Rinse 0.1%	Dental Rinse	Stan Care
Xylometazoline (Panel)	Nasal 0.1%	Decongestant	Otrivin

* Systemic drugs were covered in Part II of this series.

** Panel = FDA Advisory Panel on OTC Drugs, NDA = Shifted via New Drug Application Mechanism

8. Keep all medicines out of the reach of children.
9. In case of accidental ingestion by a child, call your doctor or poison control center immediately.

Patient Counseling for Topical Decongestants

1. This medicine is used for temporary relief of nasal congestion or stuffiness from colds, hay fever and sinusitis.
2. Do *not* exceed the recommended dosage; burning, stinging, or increased nasal discharge may occur.
3. Do *not* use the adult strengths of this medicine in children under 6 years of age, or, the child strength in children under 2 years of age unless directed by your doctor.
5. Keep all medicine containers tightly closed.
6. Do *not* use the solution if it is discolored.
7. The use of the dropper or spray bottle by more than one person may spread infections.

Proper Use of Nose Drops

1. Blow your nose gently just before using this medicine.
2. Squeeze the rubber bulb on the dropper to draw up 2 to 3 drops of medicine.
3. Sit in a chair with your head tilted back.
4. Insert the dropper into one nostril and squeeze the medicine into your nose. Repeat in your other nostril.
5. Then lean your head forward toward your knees. Inhale and hold your breath for a few seconds.
6. Be extra careful not to touch the side of the dropper to the side of your nose.
7. After use, rinse the dropper with hot water, wipe it clean and carefully replace it into the bottle.

Proper Use of Nose Sprays

1. If this product is a metered pump, it must be primed several times when first opened.
2. Blow your nose gently just before using.



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3. Hold your head upright to spray.
4. Remove the protective cap and insert the nosepiece into one nostril pointing it slightly inward.
5. Administer 2 to 3 sprays as directed on the bottle, inhaling as you are squeezing the container or using the pump.
6. Repeat in your other nostril.
7. After use, rinse the nasal tip with hot water, wipe it clean and replace the protective cap.
8. Do *not* share the spray unit with another person.

Patient Counseling for Ophthalmic Decongestants

1. This medicine is used to remove redness of the eye due to minor eye irritation.
2. Most people do not experience side effects from this product, but sometimes mild stinging or temporary blurred vision occur.
3. If you experience eye pain, changes in vision, continued redness or irritation of the eye or the condition persists for 3 days or worsens, STOP using the eye drops and consult your doctor.
4. Do *not* exceed the recommended dosage.
5. Do *not* use these eye drops if they have changed color, are cloudy or contain crystals.
6. Do *not* use this medication without checking with your doctor if you have glaucoma.
7. Do *not* use while wearing contact lenses.
8. Do *not* use in children under 6 years of age unless directed by your doctor.

Proper Use of Eye Drops

1. Wash your hands with soap and water before using the eye drops.
2. To apply the drops, gently pull your lower eyelid downward to form a pouch.
3. Tilt your head backward, hold the dropper tip above your eye,

Potential Prescription to OTC Switch Drugs

Generic Name	Trade Name	Indication
Acyclovir	Zovirax	Herpes simplex
Astemizole	Hismanal	Allergy
Azatadine	Optimine	Allergy
Benzonate	various	Antitussive
Butaconazole	Femstat	Fungal infections
Carisoprodol	Rela, Soma	Muscle spasms
Chloramphenicol, etc.	Chloromycetin, etc.	Eyeinfection
Cholestyramine	Questran	Cholesterol lowering
Chlorzoxazone	Paraflex	Muscle spasms
Cimetidine	Tagamet	Heartburn
Clotrimazole lozenges	Cotrimin	Thrush
Colestipol	Colestid	Cholesterol lowering
Corticosteroids, nasal	Beconase, etc.	Allergy
Cromolyn inhaler	Intal	Asthma
Cromolyn nasal	Nasalcrom	Allergy
Cromolyn eye	Opticrom	Allergy
Cromolyn oral	Gastrocrom	Gastritis
Cyclobenzaprine	Flexeril, etc.	Muscle spasm
Cyproheptadine	Periactin, etc.	Itching
Dexchlorpheniramine	Polaramine	Allergy
Dicyclomine	Bentyl, etc.	Irritable bowel
Diflunisal	Dolobid, etc.	Pain
Econazole	Spectazole	Fungal infections
Epinephrine injection	EpiPen	Insect bites/stings
Erythritol dinitrate	Cardiate, etc.	Angina
Erythromycin topical	various	Acne
Estrogen/progestin	various	Hormone replacement
Famotidine	Pepcid	Heartburn
Fenoprofen	Nalfon, etc.	Pain
Hydroxyzine	Atarax, etc.	Allergy
Ibuprofen topical	various	Muscle/joint pain
Indomethacin topical	various	Muscle/joint pain
Ipratropium	Atrovent	Asthma
Isosorbide dinitrate	Isordil	Angina
Ketoconazole topical	Nizoral	Fungal infections
Ketoprofen	Orudis	Pain
Lindane	Kwell, etc.	Pediculicide
Loratidine	Claritin	Allergy
Metaproterenol	Alupent, Metaprel	Asthma
Methenamine	Mandelamine, etc.	UTIs
Methocarbamol	Robaxin, etc.	Muscle spasms
Metoclopramide	Reglan, etc.	Non-ulcer dyspepsia
Minoxidil, topical	Rogaine	Male-pattern baldness
Naproxen	Anaprox	Pain
Nicotine gum	Nicorette	Smoking deterrent
Nicotine patch	Nicoderm, etc.	Smoking deterrent
Nitroglycerin SL	Nitrostat	Angina
Nizatidine	Axid	Heartburn
Nystatin	Mycostatin, etc.	Fungal infections
Orphenadrine	Norflex, etc.	Muscle spasms
Phenazopyridine	Pyridium, etc.	Urinary analgesic
Piroxicam topical	Feldene	Muscle/joint pain
Podofilox	Condylox	Genital warts
Prometazine oral	Phenergan, etc.	Antitussive
Promethazine rectal	Phenergan, etc.	Antiemetic
Propantheline	Probanthine, etc.	Irritable bowel
Propranolol	Inderal, etc.	Stage fright
Ranitidine	Zantac	Heartburn
Sucralfate	Carafate	Ulcers
Sulfacetamide eye	Sulamyd, etc.	Eye infections
Sulindac	Clinoril, etc.	Arthritis

Table Two

and place 1 or 2 drops inside your lower lid.

4. Do *not* touch the dropper tip to any surface.
5. Release your lower lid. Try not to blink for a few seconds. Replace the cap on the bottle and store it out of the reach of children.
6. Do *not* rinse the dropper. You may contaminate the medicine.

Patient Counseling for Oral Anesthetics

1. This medicine is used for temporary relief of occasional minor irritation, pain, sore mouth or sore throat.
2. The lozenge should be dissolved slowly in your mouth. Do *not* chew or swallow the lozenge whole.
3. The spray should be used in your mouth and throat as directed on the product label.
4. Possible side effects from this medicine include numbness of the mouth and throat.
5. If sore throat is severe, lasts for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, call your doctor.
6. Do *not* give to children under 2 years of age unless directed by your doctor.

Patient Counseling for Fluoride Mouth Rinses

1. This medicine is used to control cavities when water supplies are low in fluoride content.
2. Rinse your mouth after brushing, flossing, and prior to sleep.
3. Spit out any excess. Do *not* SWALLOW.
4. Do *not* eat, drink or rinse your mouth for 30 minutes after using.
5. Do *not* dilute this rinse in a glass; use a plastic or the cup supplied by the manufacturer.

Prescription Drugs in the U.S. that are OTC in Canada, Great Britain or Australia

Astemizole	Metaproterenol
Cholestyramine	Methenamine
Cyproheptadine	Naproxen
Dicyclomine	Methocarbamol
Econazole	Nicotine Gum
Epinephrine	Nystatin
Ibuprofen topical	Sucralfat
Isosorbide	Sulfacetamide
dinitrate	eye drops
Ketoconazole	Terbutaline
topical	Theophylline
Loratidine	Tripelennamine

Table Three

6. Possible side effects from this medicine include excess saliva, nausea, vomiting, stomach pain, diarrhea, tooth staining.
7. Call your dentist if your teeth become mottled or stained.
8. Do *not* use if drinking water has a fluoride content greater than 0.7 parts per million (pm).
9. Do *not* use the 1 mg rinse product in children under 6 or when the drinking water fluoride content is equal to or greater than 0.3 pm.
10. Do *not* use if you are on a low salt diet without first checking with your dentist.
11. Gum tissue may be sensitive to some flavors or the alcohol content of this medicine.
12. If more than an ounce is accidentally swallowed, give several glasses of milk and contact your doctor or poison control center for instructions.

Patients Counseling for Topical Antifungals

1. This medicine is used to treat fungal infections such as

athlete's foot, jock itch, and ringworm.

2. Wash your hands before and after using this medicine.
3. Wash the skin area with soap and water and pat dry before using this medicine.
4. Apply a small amount of medicine over the affected area morning and night or as directed by your doctor.
5. For athlete's foot, pay special attention to the areas between your toes. It is best to wear well ventilated shoes and to change your socks every day.
6. Athlete's foot and ringworm should clear up in 4 weeks and jock itch within 2 weeks. If your condition persists or worsens, or if you have a constant irritation, such as burning or itching that was not present before you started this medicine, call your doctor before using this product.
7. If you have diabetes or decreased circulation, consult your doctor before using this product.
8. Apply with caution to blistered or raw skin, oozing skin, or skin over a deep puncture wound.
9. Do *not* apply other creams, lotions or cosmetics on top of or underneath this medicine.
10. Do *not* use this medicine in children under 2 years of age unless directed by your doctor.

Patient Counseling for Vaginal Antifungals

1. This medicine is used to treat vaginal candidiasis ("yeast") infections after diagnosis by a doctor. If this is the first time you have had vaginal itch and discomfort, consult your doctor.
2. If a doctor has previously diagnosed the same symptoms as a yeast infection, use the medicine as directed for 7 consecutive days.

3. Follow the instructions for proper use enclosed in the package. Insert high into the vagina except during pregnancy.
4. Complete the full course of therapy. Use continuously, even during menstrual period.
5. If symptoms persist longer than 7 days or worsen, or if you have a constant irritation, such as burning or itching that was not present before you started this medicine, call your doctor.
6. Diabetes, chronic antibiotic therapy, pregnancy, steroid use and oral contraceptive use may cause chronic and recurrent yeast infections.
7. Refrain from sexual intercourse during treatment, or your male partner should use a condom to avoid the risk of infection.
8. Wear a sanitary napkin to prevent staining of clothing due to seepage or leakage. Do not wear a tampon as it may absorb the medicine and interfere with its action.

How to Use Vaginal Suppositories and Tablets

1. Wash your hands with soap and water before and after using this medicine.
2. Cleanse the vaginal area and pat dry.
3. Remove the wrapper from the suppository/tablet.
4. Moisten the suppository/tablet with warm water.
5. If an applicator is used, place the small end of the suppository or tablet into the applicator.
6. Lie on your back with knees bent and slightly spread apart. Insert the barrel, containing the medicine, gently into your vagina with a downward motion as far as it will comfortably go.
7. Press the plunger gently to deposit the suppository/tablet into your vagina. With the plunger still pressed, remove the applicator.
8. Pull the applicator apart for easy cleaning.
9. Wash the two parts with soap and lukewarm water, then dry.
10. Do *not* boil or soak in very hot water.
11. Reassemble by gently pushing the plunger back into the barrel as far as it will go.

How To Use Vaginal Creams

1. Wash your hands with soap and water before and after using this medicine.
2. Follow any directions for use provided by the manufacturer.
3. To open the tube, puncture the tube with the point inside the cap. Screw the applicator onto the tube.
4. Squeeze the tube from the bottom until the plunger is extended to the appropriate mark for the prescribed dose.

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5. Unscrew the filled applicator from the tube and insert the barrel gently into your vagina with a downward motion as far as it will comfortably go.
6. This is done easiest if you are lying on your back with your legs spread apart and your knees bent.
7. Push the plunger all the way to deposit the cream into the vagina. With the plunger still pressed, remove the applicator.
8. Pull the applicator apart for easy cleaning.
9. Wash the two parts with soap and lukewarm water, then dry.
10. Do *not* boil or soak in very hot water.
11. Reassemble by gently pushing the plunger back into the barrel as far as it will go.
12. Place the cap on the tube and close tightly.

Patient Counseling for Topical Anti-inflammatory Agents

1. This medicine is used for temporary relief of minor skin irritation, itching and rashes due to eczema, insect bites, poison ivy, oak or sumac, allergic inflammation from soaps, detergents, cosmetics or jewelry; and other skin irritations.
2. Apply a small amount of the medicine as a thin film over the affected area 3 or 4 times a day. Rub in gently.
3. The spray is best suited for hairy areas. Shake well before using. Hold the can upright about 6 to 8 inches from affected area. Spray for 2 to 3 seconds.
4. Wash your hands before and after using this medicine.
5. Washing the skin area with soap and water and patting dry before use may increase the effectiveness of this medicine.
6. If your condition persists longer than 7 days or worsens, or if you have a constant irritation, such as burning or itching that was not present before you started

using this medication, call your doctor.

7. Do *not* apply other creams, lotions or cosmetics on top of or underneath this medicine.
8. Do *not* use near your mouth or eyes.
9. Do *not* use on children under 2 years of age unless directed by your doctor.

Patient Counseling for Pediculicides

1. This medicine is used to treat head lice.
2. Wash your hands before and after using this medicine.
3. This medicine is applied to the hair after it has been washed with your regular shampoo, rinsed and towel dried.
4. Saturate your scalp and leave on your hair for 10 minutes.
5. Then rinse it off immediately.
6. If lice are observed 7 days after application of this medicine, repeat the treatment.
7. Use the special precision comb supplied with the medicine to remove dead lice and eggs after application.
8. Soak combs and brushes in hot water (above 130° F) for 5 to 10 minutes after each use.
9. At the time of treatment, all personal headgear, scarfs, clothing, and bed linen should be laundered in hot water and dried in a clothes dryer, or dry cleaned.
10. Articles that cannot be laundered can be placed in a tightly sealed plastic bag for 2 weeks or sprayed with product specifically for that use.
11. Rooms occupied by the infected person should be thoroughly vacuumed.
12. Possible side effects from this product include allergic skin irritation, rash, itching, burning, stinging, tingling, numbness, swelling, discomfort, or redness. If these occur, contact your doctor.
13. Do *not* use this medicine in or

near your eyes or mouth.

14. Do *not* use on children under 2 years of age unless directed by your doctor.
15. Do *not* leave children unattended after applying this product on their heads.

Adapted from the *Pharmex PALS* (Patient Advisory Leaflets). For more information, call (800) 233-0585. To earn continuing education credit for this article, please turn to page 30 of this issue.

Pharmacists Must Be Perfect

David B. Brushwood, R.Ph., J.D.



The Court of Appeals of Colorado has recently issued an opinion in which it affirms a lower court verdict in favor of a patient in a lawsuit brought against the University of Colorado Health Science Center. The allegations in the case indicate that a physician ordered gentamicin for a child, and that through an error by the hospital pharmacy in preparing the medication, the child received approximately five times the prescribed amount. Allegedly, the child developed a moderately severe sensorineural bilateral hearing loss.

At the trial that ensued, the jury awarded the plaintiff \$295,000 but that amount was reduced to \$150,000 due to a law in Colorado that prohibits the state from being held liable for more than \$150,000.

On appeal, of particular concern to the hospital was a ruling made by the judge at the close of the presentation of evidence. The trial judge had granted a directed verdict in favor of the plaintiff, ruling that as a matter of law the hospital pharmacists were negligent. In effect, this ruling took the issue of negligence away from the jury, permitting them to decide only how much damages to award. While the jury resolves fact questions, the judge resolves law questions, and this ruling meant that the fact of having made an error indicated that negligence must have occurred in the hospital pharmacy.

The hospital's argument on appeal was that some error by humans is inevitable, no matter how careful one does one's job. The hospital simply wanted the jury to hear the "nobody is perfect" argument, and possibly to rule that even though a mistake occurred, there was no negligence, because standard procedures were being followed. But the court rejected this argument.

The result in this case is a rule of law that says any time a mistake occurs in order processing the pharmacist must have been negligent as a matter of law. It is a rule of law that demands perfection, even though perfection is humanly impossible. Under this rule, pharmacy is a "no mistakes allowed" profession.

Based on: *DeCordova v. State of Colorado*, 1994 Westlaw 57855 (Colo. App. February 24, 1994). Copyright 1994, David B. Brushwood. All rights reserved. Reprinted from *Dickinson's Pharmacy*, April, 1994.

About the Author

David Brushwood is Professor of Pharmacy Health Care Administration at the University of Florida. His articles on cases affecting pharmacies and pharmacy are provided as a courtesy to state pharmacist associations. Questions on legal issues affecting Maryland practice should be directed to your legal representative or the Maryland State Board of Pharmacy.

Continuing Education

Continuing Education Quiz

May 1994 -- Topical OTCs

This month's questions are taken from the article on topical Rx-to-OTC switch products that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members \$10.00). The completed quiz for this issue must be received by October 30, 1994. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

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1. The recommended time limit for self-medication with topical decongestants is:
 - a. 3 days
 - b. 5 days
 - c. 7 days
 - d. 10 days
2. The local anesthetic that has been switched to OTC status in a lozenge dosage form is:
 - a. lidocaine
 - b. tetracaine
 - c. dyclonine
 - d. benzocaine
3. The trade name for an OTC product containing the local anesthetic referred to above is:
 - a. Chloraseptic
 - b. Halls
 - c. CepaStat
 - d. Sucrets
4. All of the following are correct statements for counseling women who are self-treating vaginal yeast infections *except*:
 - a. If this is the first time you have had vaginal itch and discomfort, consult your doctor before selecting an OTC product.
 - b. If a doctor has previously diagnosed the same symptoms as a yeast infection, use this medicine as directed for 3 days.
 - c. If symptoms persist longer than 7 days or worsens, or if you have constant irritation that was not present before you started to use this medicine, call your doctor.
 - d. Wear a sanitary napkin to prevent staining of clothing due to seepage or leakage, but do not wear a tampon as it may adsorb the medicine.
5. Persons using NIX to treat head lice should saturate the scalp and leave it on their head for:
 - a. 10 minutes
 - b. 20 minutes
 - c. 30 minutes
 - d. 60 minutes
6. All of the following are correct statements for counseling on the proper use of nose drops *except*:
 - a. blow your nose gently just before using
 - b. Squeeze the rubber bulb on the dropper to draw up 8 to 10 drops of medicine.
 - c. Sit in a chair with your head tilted back.
 - d. Insert the drops into one nostril and squeeze the medicine into your nose. Repeat in other nostril.
7. OTC fluoride rinses should not be used if the drinking water has a fluoride content greater than:
 - a. 0.007 ppm
 - b. 0.07 ppm
 - c. 0.7 ppm
 - d. 7 ppm
8. All of the following are antifungals that have been switched from Rx-only to OTC status *except*:
 - a. Gyne-Lotrimin
 - b. Monistat
 - c. Mycelex
 - d. Mycostatin
9. Individuals self treating athlete's foot should pay special attention to the area:
 - a. above the arch
 - b. around the toes
 - c. between the toes
 - d. under the soles

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION, organized in 1926, meets every third Wednesday of the month at Horn and Horn Smorgasbord on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call John Ayd at (410) 661-2383 for details.

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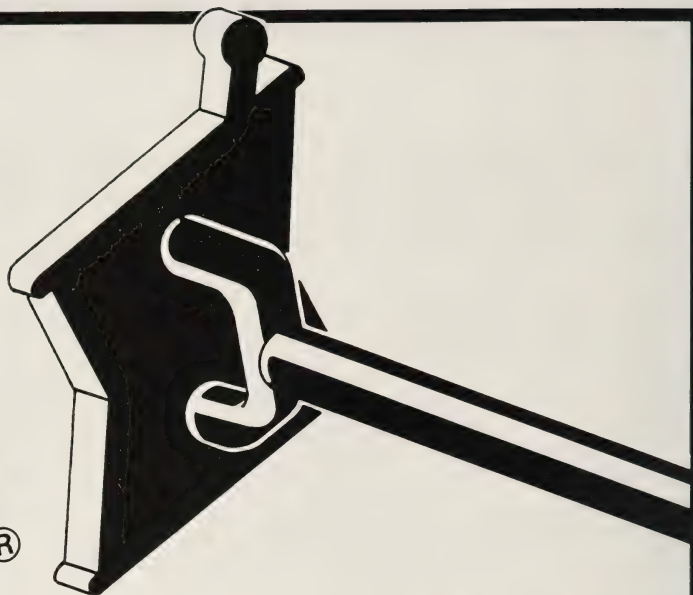
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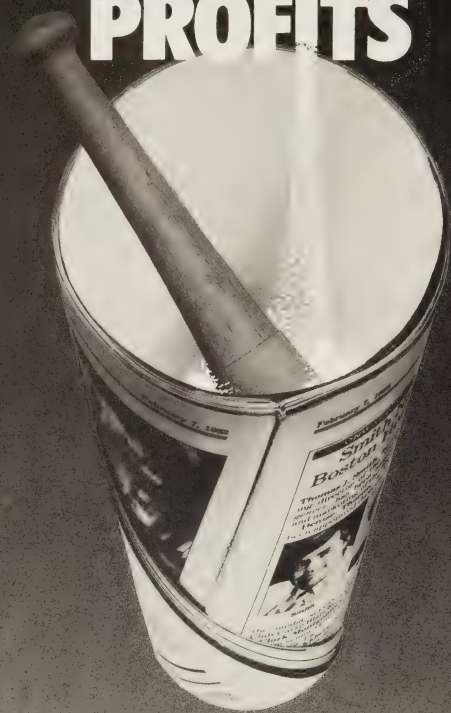
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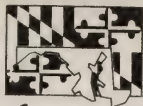
*The Debate Over
Technician Certification*

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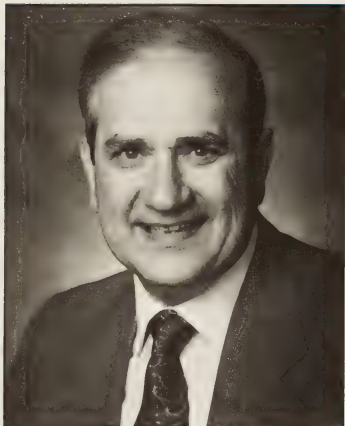
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President's Commentary

Howard Schiff, P.D.



What is a pharmacy technician? Regardless of what you might think, they do not exist under Maryland law. In Maryland, a pharmacy technician is what you, the pharmacist say he or she is. It is your responsibility to hire, train, delegate and delineate tasks, oversee and supervise. You, the professional, are responsible for any errors in judgement or mistakes. This is essentially the position of the Maryland Board of Pharmacy.

With OBRA '90's pharmaceutical care and patient counseling requirements, technicians are assuming an even greater role than ever before. They enable pharmacists to be more patient focused.

The question is, what do we do with them? Should technicians be registered (defined as including a person's name in a registry with the state board), certified (recognition by a non-governmental agency or organization after meeting certain qualifications), or licensed (a governmental agency grants permission to a person who demonstrates competency)?

The Community Retail Pharmacy Working Group, a coalition of NARD and NACDS, feels that a push by the Illinois Council of Hospital Pharmacists, the Michigan Pharmacists, APhA and ASHP for a national voluntary technician certification program is driven by the economic interests of the sponsoring organizations. Monies are derived from the fees paid by the techs for certification. The Working Group also feel that pharmacy practice settings are too diverse for any single certification program. Several states are now grappling with technician recognition problems.

I'm not so sure about the economics of certification but I am sure about the diversity among practice settings. A hospital technician may have far different responsibilities than one in a community setting.

What I really fear however is the creation of a paraprofessional group that could exacerbate even tougher economic times in the future. We already have reduced reimbursements from third parties. Interactive television and unit-of-use packages are technologies available today. Who knows what cost saving measures some bureaucrat will dream up, even at the cost of public safety. These are all factors which increase the use of techs. Pharmacists' salaries have always been determined by supply and demand. If a tech, with the support of electronics, can do the job at half the salary, will we need all the pharmacists we currently have or will have?

Many technicians begin working in other areas of a pharmacy before being promoted to that status. Usually this is because they have shown both ability and interest. They have been trained and promoted from within to meet the needs of the individual pharmacy and pharmacist. Others have started as techs and also been trained on the job. Let's keep it that way. **R**

Voluntary Certification of Technicians

Community Retail Pharmacy Committee

NARD/NACDS Community Retail Pharmacy Working Group



OBRA 1990. Health care reform. Patient counseling. DUR. Pharmaceutical care. Patient outcomes. What do all of these phrases and terms have in common?

The common denominator in all of the above terms is that it will require the full utilization of pharmacy technicians working under the direct supervision of a pharmacist to allow the pharmacist to assume a greater patient-focused role in pharmacy practice.

The Community Retail Pharmacy Working Group, representing the National Association of Chain Drug Stores (NACDS) and NARD, was formed in early 1993 to address community pharmacy practice issues. The Working Group represents 112,000 community pharmacists practicing in over 60,000 pharmacies nationwide. Recognizing the need for the greater utilization of pharmacy technicians, the Working Group has

prepared a document, entitled "Answers to Commonly Asked Questions about the Voluntary Certification of Pharmacy Technicians."

The Working Group prepared this document to clearly delineate many of the issues surrounding pharmacy technicians, including the development of a national, voluntary certification program for technicians in all practice settings. The Working Group believes that the pharmacy profession is highly diverse and is becoming even more so. This applies to pharmacy technicians as well. Recognizing this fact, the working Group believes it is unrealistic to educate an individual -- a pharmacy technician -- to be "all things to all people."

Background

The proper utilization of pharmacy technicians has been a long-standing issue in pharmacy practice. Additionally, the implementation of patient counseling regulations by numerous state boards of pharmacy in recent years has resulted in the need for greater utilization of pharmacy technicians by community practitioners. The time required for pharmacists to provide patient counseling necessitates the assistance of technicians in dispensing-related tasks. Evidence of this growing interest in technicians abounds and at the 1993 National Association of Boards of Pharmacy Annual Meeting, 15 separate resolutions were presented related to pharmacy technicians.

The initial efforts of the Working Group were focused on discussions with NABP and its Executives Committee relative to the issue of pharmacy technicians, specifically how they should be trained and recognized.

In December 1993, four pharmacy organizations (American Pharmaceutical Association, American Society of Hospital Pharmacists, Illinois Council of Hospital Pharmacists, and Michigan Pharmacists Association) announced they were together to establish a national voluntary certification program to "accommodate pharmacy technicians in all sectors of pharmacy practice." This certification would be awarded after the technician satisfactorily completed a certification examination.

The Working Group strongly opposes the national voluntary certification program being proposed as inappropriate, unnecessary, and not reflecting the unique needs of community retail pharmacy practice. Since this program was announced, community pharmacists have raised a number of important questions that the Working Group has assimilated and answered on the following pages in an attempt to address their concerns. In developing these answers, the Working Group has examined factual data and statistics, and talked with people who would be affected by changes relevant to the training and recognition of pharmacy technicians.

Continued on page 7...

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There seems to be considerable confusion regarding how pharmacy technicians should be recognized. What are the differences between registration, certification and licensure of pharmacy technicians?

What are the "predetermined qualifications" for pharmacy technicians that are mentioned above?

Why are the Illinois Council of Hospital Pharmacists, the Michigan Pharmacists Association, APhA, and ASHP pushing to create a certification program with an examination for all practice settings?

The three definitions below are generally accepted by the pharmacy profession. Note: While registration and certification exist in some states, licensure (by examination) does *not* exist in any state.

Registration is the process of including a person's name on a registry. With regard to pharmacy technicians, the State Board of Pharmacy would maintain a registry of technicians and require the technician or employer to notify the Board within a certain period of time whenever the technician changes pharmacy location. This would enable the State Board of Pharmacy to track where pharmacy technicians are employed.

Certification is the process by which a nongovernmental agency or organization grants recognition to an individual who has met certain predetermined qualifications specified by that agency or organization.

Licensure is the process by which a government agency grants permission to an individual to engage in a given occupation upon determining that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety and welfare will be reasonably well protected.

The term "predetermined qualifications" generally means that the technician has successfully completed the certification examination by achieving a predetermined passing grade. In some states, the Board of Pharmacy may determine other qualifications technicians must meet regardless of whether they are certified. These additional qualifications typically may pertain to age and whether they have a high school diploma or its equivalent.

Clearly, these four groups recognize the fact that the current number of pharmacy technicians in the United States is estimated to be between 150,000 and 200,000 and that such a large audience for certification programs/examinations would be a significant revenue source for these organizations.

However, the Community Retail Pharmacy Working Group believes that any voluntary certification program should be driven primarily by pharmacy practice needs, not the economic interests of any segment of the profession.

A report prepared in February 1993 for the APhA Board of Pharmaceutical Specialties by a consultant states:

"My own experience suggests that about one to three percent of any specialty group takes a certification examination in a year. This would support an estimate of anywhere from 1,500 to 10,000 candidates annually. For the purposes of this report, the estimate of about 5,000 candidates annually is used. The report goes on to state: Assuming that an average certified pharmacy technician has a salary of about \$20,000 per year would suggest an examination fee of \$100. A \$25 non-refundable registration fee might be added to this for a total of \$125. If 5,000 candidates were tested in one year, this would mean a total revenue from candidate fees of about \$625,000. If it appears that institutions that employ pharmacy technicians are willing to reimburse them for taking the test, the candidate fee might be placed slightly higher."

In short, it appears that economics could well be the driving force behind this certification movement. Such economically-driven decisions do not have the best interest of pharmacy technicians or the pharmacy profession in mind.

What are the fundamental reasons why the Community Retail Pharmacy Working Group opposes a national, voluntary certification program for pharmacy technicians?

Will voluntary pharmacy technician certification lead to mandatory certification and ultimately to licensure? Does the National Association of Boards of Pharmacy (NABP) support either a voluntary or mandatory certification program?

Pharmacy practice settings are highly diverse. A single, national, voluntary certification program cannot prepare pharmacy technicians to work in every possible practice setting.

Also, pharmacy employers and owners are very satisfied with the skills demonstrated by technicians trained in their community pharmacies.

The Community Retail Pharmacy Working Group is concerned with the two current voluntary certifications programs that culminate in examinations. It is extremely likely that these two current examinations will, in large measure, be used to develop the single, national certification program and examination. In order to prepare and pass these examinations today, the level of knowledge necessary parallels to a great extent the knowledge a pharmacy graduate must possess to pass the national licensure examination (NABPLEX).

The level of knowledge needed to pass the certification examinations is outlined in the latest edition of the Pharmacy Certified Technician Manual that prepares technicians for the certification examination.

We strongly believe these competencies go far beyond what is needed to be a community pharmacy technician.

These competencies include, but are not limited to, those listed below:

Identify the pharmacological action of diuretics.

Differentiate between iron deficiency anemia and megaloblastic anemia with regard to changes in circulating cells in blood resulting effects on body tissues and treatment.

Differentiate between systemic and external fungal infections with regard to sites of infection and ease of treatment.

List the main actions of prostaglandin antagonists

Describe provisions of the Nonprofit Institutions Act

Considering the economics involved it certainly would seem likely that voluntary pharmacy technician certification programs could very well lead to mandatory technicians certification programs and ultimately licensure. However, NABP, the recognized licensing body for the pharmacy profession, has, to date limited its support solely to the registration of pharmacy technicians. Resolutions that addressed licensure and a national examination program for technicians were rejected by the 1993 NABP House of Delegates. In the future, if additional actions regarding technicians are necessary, NABP likely would be the organization to implement procedures to assure the competencies and qualifications of pharmacy technicians. But to date, NABP has not taken a position relative to a national voluntary or mandatory pharmacy technician certification program.

Reference: NABP Resolution 89-15-93 Recognition and Uniform Designation of Pharmacy Technicians; 89-16-93 Supervision and Registration of Pharmacy Technicians; 89-17-93 Training of Pharmacy Technicians; 89-18-93 Technicians: Revision of the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy; and 89-20-93 Pharmacy Technicians: Competence Assessment, Disciplinary Clearinghouse, and Qualifications Verification (NABP Annual Meeting, May 1993, Baltimore, Maryland).

Will voluntary pharmacy technician certification programs lead to a separate category of paraprofessionals within the profession of pharmacy? Will these professionals then seek greater responsibility and attempt to move away from performing tasks under a pharmacist's supervision?

The issue of increasing pharmacy technician autonomy is already beginning to surface. An example of this can be found in an advertisement in the "Career Opportunities" section of a recent APhA newsletter, *Pharmacy Today* (December 6, 1993; page 12) read:

Pharmacist Assistant -- Mix and dispense prescribed medicines & pharmaceutical preparations in the absence of or under supervision of Hospital Pharmacist...(emphasis added)

Additionally, the President of the American Association of Colleges of Pharmacy (AACP) in his Presidential Address delivered at the AACP Annual Meeting, July 14, 1993, made the following public remarks:

It is difficult to justify why a pharmacist must not only be physically present, but actually watching a single licensed technician count ... I anticipate that dispensing practices will be carried out by a credentialed pharmacy technician, who will communicate via video satellite, computer, or audio hook-up...

Further, an editorial in the March/April 1993 issue of *Journal of Pharmacy Technology* predicted that by the year 2000, pharmacy technicians will be initiating role changes for themselves. The editorial went on to list several reasons why pharmacists will be losing more control over what pharmacy technicians do.

The Community Retail Pharmacy Working Group believes these changes are not in the best interests of the profession. Pharmacy technicians have an important role to play in pharmacy practice, but the ultimate responsibility for a technician's actions must continue to rest with the supervising pharmacist.

Will the individuals who have already taken a state-administered, voluntary certification program automatically be grandfathered?

This is a very good question. In fact, the four groups that made the announcement to offer one national, voluntary certification program for all of pharmacy, anticipated this question and answered it by stating, "We share a desire to accommodate the interests of technicians who have been certified under one of the state programs." It is too early to determine how this will be done.

The unwritten answer, however, which was given verbally by an ASHP spokesperson to several members of the Community Retail Pharmacy Working Group was: "We are not inclined to do that." In other words, it appears that pharmacy technicians who are currently certified will need to be re-certified by passing this singular examination.

Will certified pharmacy technicians command higher salaries?

Pharmacy technicians can expect to receive salary increases on the basis of job performance and seniority. We are concerned, though, that some pharmacy technicians may be misled into thinking that they will be able to command higher salaries simply by virtue of becoming certified. Salary decisions will depend on individual employers and the contribution the technician makes in the practice setting.

What is the likely cost (in terms of dollars and preparation time) of a national certification examination?

So what is the Community Retail Pharmacy Working Group advocating with respect to pharmacy technicians?

The four organizations proposing a single, national, voluntary certification examination state that the costs to take this examination remain to be determined.

Current certification examinations developed by the Illinois Council of Hospital Pharmacists and the Michigan Pharmacists Association cost \$85 and \$50 respectively. The Pharmacy Certified Technician Manual prepares a candidate for the Michigan Pharmacists Association version of the examination. This text costs \$20 plus shipping and handling. Additional direct and indirect costs the technician may incur include registration fees for review seminars and the time needed to study for, travel to, and take the examination.

Each supervising pharmacist should be free to determine what tasks technicians perform and how they should be trained to perform those tasks in accordance with their State Pharmacy Practice Act and regulations. Most community practice settings have developed on-the-job training programs, and /or supplemental off-site training programs. The latter usually consists of a two-week program that takes place in model pharmacy complete with computers. The trainer works with the pharmacy technician until he/she successfully completes the program. In most instances, the trainee has worked at the pharmacy before becoming a technician and therefore has already demonstrated proficiency and a commitment to move into a position that requires technician skills. Additionally, the Community Retail Pharmacy Working Group is developing a Community Pharmacy Technician Training Manual that can be used by pharmacists as a tool to support pharmacy technician training in the community setting.

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Pharmacists Not Only Count

Results of Schering Report XVI

Jack Robbins, Ph.D., Director, Pharmacy Affairs, Schering Laboratories



Patients whose only counseling about taking prescription medications came from their pharmacists reported the highest rate of medication compliance, a near-perfect 96 percent.

This was one of the major findings of a new, independent survey commissioned by Schering Laboratories.

Patients counseled by both physicians and pharmacists reported a compliance rate of 93 percent, followed by counseling by the physician alone (89 percent) and patients not counseled by either (77 percent).

Both the doctor and the pharmacist are important in encouraging patient compliance -- taking medication as prescribed. But the study confirms that the pharmacist, even on his or her own, is uniquely positioned to get results.

Schering Report XVI -- "OBRA '90: Pharmacists Not Only Count, But They Also Make a Difference" -- focuses on what counseling by pharmacists is mandated and the effectiveness of that counseling in light of the provisions of OBRA '90 (The Omnibus Budget Reconciliation Act of 1990).

Counseling has evolved from a good idea to the law of the land. OBRA originally mandated pharmacists to provide counseling to Medicaid patient at all practice sites. The scope has now been expanded in many states to include all patients, and to encourage profile monitoring as a means of achieving greater cost-effectiveness.

Improper compliance is estimated to cost the U.S. economy more than

\$100 billion in lost productivity and extra medical costs annually. Beyond the economic costs, the underuse or overuse of prescribed medicines can lead to serious illness and death for thousands of patients every year.

Schering Reports over the years confirm that counseling is actually what pharmacist like most about their profession. So with OBRA on the books, pharmacists will play a unique role in encouraging proper patient compliance.

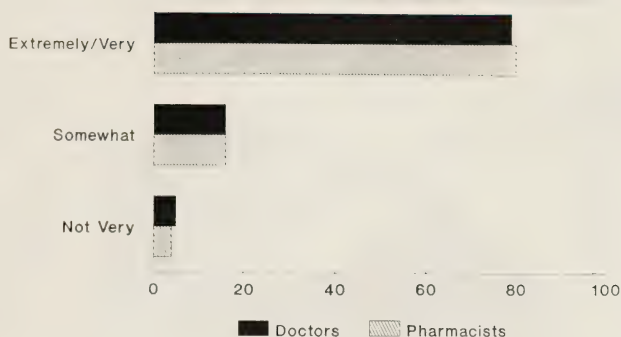
The study, based on interviews with 2,000 patients, documents just how much counseling patients receive from both doctors and pharmacists, as well as its effectiveness

Counseling is becoming increasingly important as the number of prescriptions dispensed annually in the United States edges toward the predicted 2 billion mark by year 2000. As the population ages and chronic diseases such as high blood pressure, arthritis and pulmonary diseases predominate, failure to fill and refill prescriptions will become an ever-more serious problem.

Schering Report XVI follows patients from the doctor's office to the pharmacy to their homes to study how counseling affects patient compliance. In the course of a year, eight out of 10 Americans (79 percent) visit a doctor. Over half (58 percent) receive one or more

Customer Satisfaction

Doctors vs Pharmacists



prescriptions during a typical visit.

Most patients interviewed recall being counseled by doctors on the three major factors of compliance -- dosage, frequency and duration. For both dosage and frequency, 91 percent recall receiving instructions, while 85 percent remember being told about duration.

For other aspects of counseling, few patients recall getting information from doctors. Only 52 percent were told about the potential side effects of medications; only 41 percent were cautioned on possible interactions with other medications; and only 43 percent were alerted to avoid certain foods or alcohol while taking the medicine.

Seven out of 10 patients (71 percent) recalled that the doctor advised them on having the prescription refilled.

Given the somewhat uneven scope of advice, patients generally were quite satisfied with the verbal and written instructions provided by their doctors about their most recent prescriptions. Seventy-nine percent reported being extremely or very satisfied, 16 percent as somewhat satisfied, and only 5 percent as not very satisfied.

Although the road from the doctor's office leads straight to the

pharmacy for patients with a prescription in hand, it is a road not taken by one out of 20 patients. Overall, 5.4 percent never have the prescription filled. Patients dissatisfied with their doctor's instructions were three times as likely not to have their prescriptions filled as those who were satisfied (11.6 percent to 3.8 percent).

On the issue of patient loyalty, the Schering Report revealed that most patients (78 percent) are loyal to one pharmacy, with loyalty strongest among women (83 percent) and those over 55 years of age (85 percent).

Asked what type of pharmacy they favor, patients said chain pharmacies (39 percent), independents (29 percent), supermarkets or department stores (11 percent), HMO pharmacies (11 percent) and discount store pharmacies (9 percent).

Since the likelihood of receiving counseling by a pharmacist is related to personal contact with the pharmacist, patients who pick up their own medications (70 percent) stand the best opportunity for on-the-spot counseling.

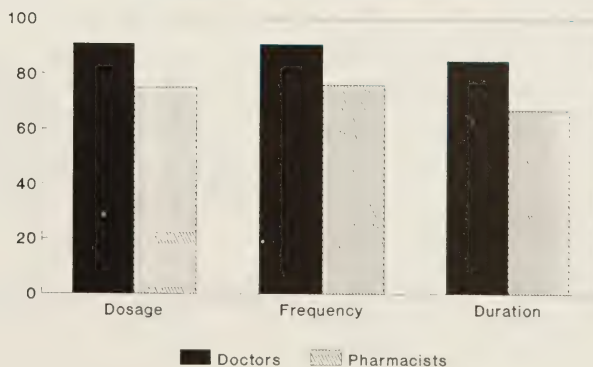
But the very people who have the most prescriptions and the most need for counseling -- those over 55 years old and Medicaid patients -- also had the lowest incidence of picking up their own prescriptions. This points up a serious potential problem for the very people most in need of counseling.

While noting that counseling means speaking to the pharmacist, the Schering study reported that only two out of five patients (42 percent) recall doing so. And the rate drops to a disturbing 33 percent among Medicaid patients.

Asked why they had not spoken to their pharmacist -- either in person or by phone -- most patients said there was simply "no need," particularly since they had used the medication before.

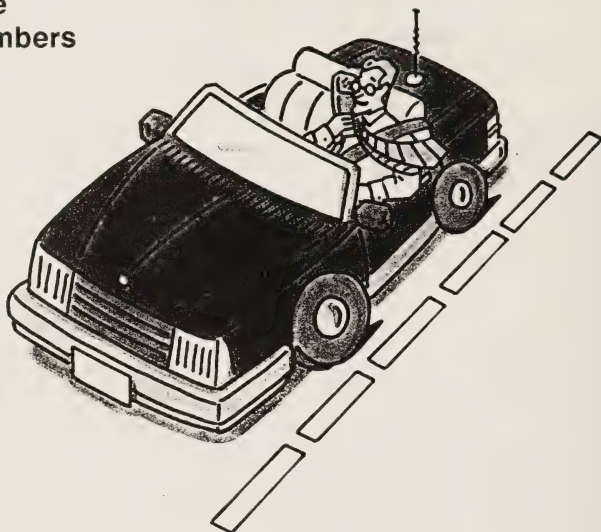
Counseling Satisfaction

Doctors vs Pharmacists



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The Schering Report also examined how pharmacists and physicians stack up on counseling patients on the basic factors of compliance. Overall, physicians scored higher on dosage (91 percent to 75 percent); on frequency (91 percent to 76 percent); and on duration (85 percent to 67 percent).

Pharmacists were more likely than doctors to advise patients on three other important areas, all mandated by OBRA: side effects of medications (62 percent); possible interactions with other medications (53 percent); and avoiding certain foods or alcohol while taking medicine (61 percent).

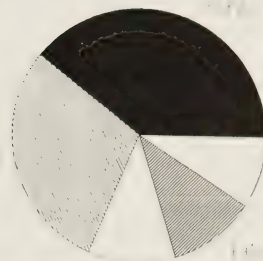
Asked to rate their satisfaction with verbal or written instructions on medications provided by pharmacists, patients said: extremely satisfied (80 percent); somewhat satisfied (16 percent); and not very satisfied (4 percent).

As for the satisfaction ratings that patients gave their physicians on the same subject, these scores were a photo finish.

Do patients take their medications exactly as prescribed? Eight of 10 patients claimed they did. Others said they follow directions pretty much (18 percent); did not really follow directions (1 percent); and did not take much or any of the medicine (3 percent).

Consumers' Preferred Pharmacies

Schering Report XVI



Women reported a better compliance record (82 percent) than men (71 percent), and patients over 55 years of age outscored those under 35 (86 percent to 69 percent).

Did patients who discussed their medication with the pharmacist feel it helped them in taking the medicine? A strong 70 percent said yes. The rates were even higher for women (74 percent versus men (64 percent); patients 55 years of age and over (76 percent); and patrons of independents (74 percent).

When patients and pharmacists do get together to discuss medications, where do the meetings take place? As revealed in the Schering Report, 80 percent of conversations take place right at the counter, 7 percent off to the side of the counter, and just 3 percent in a designated area set aside for counseling.

Would patients feel more comfortable talking about their prescriptions in a separate counseling area? The affirmatives had a slight edge (51 percent).

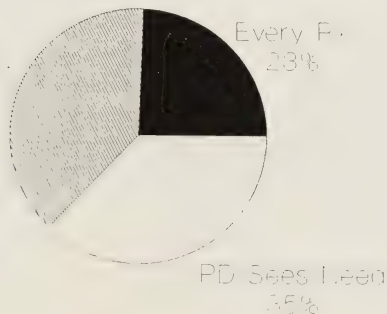
When asked under what circumstances their pharmacists should talk personally to them about their prescription, patients said: every time a prescription is filled (23 percent); only if the patient asks (36 percent); and only when the pharmacist thinks it is necessary (35 percent).

With only one in four patients opting for universal counseling, it appears there is a big education job to be done, on both sides of the counter.

Do patients feel that their discussions with pharmacists helped improve their medical problems? Of patients who patronize independent pharmacies and spoke to a pharmacist, 51 percent agreed,

How Often Should I Counsel?

Patients' Perspectives



contrasted with only 39 percent of chain pharmacy patrons who were counseled by a pharmacist. Only 35 percent of patrons of supermarket pharmacies said that counseling by their pharmacist improved their medical condition.

Underscoring the expectation that patients will show an increased willingness -- and even acceptance -- of pharmacists' counseling is their high regard for pharmacists as caring and helpful professionals.

Patients "strongly agree" (63 percent) that the pharmacist's verbal instructions are very clear and complete. Fifty-three percent strongly agree that the pharmacist, while usually busy, will spend as much time as needed to discuss the prescription. Forty-seven percent strongly agreed that pharmacists really care about them and how they feel.

These answers strongly suggest that an openness to counseling is already in place, so patients are ready to enter the new age of mandatory counseling.

With OBRA calling for improved collection and maintenance of patient profiles, the patient's willingness to provide information becomes a crucial issue in maintaining up-to-date records, the Schering Report noted.

Most patients (77 percent) said they were willing to provide pharmacists with information on their health and medical status. However, even with over a year of mandatory counseling under OBRA, Medicaid patients seem somewhat less enthusiastic (73 percent) than others.

The findings indicate clearly that both the physician and the pharmacist are important factors -- and share primary responsibility -- in encouraging compliance.

With the mandatory provisions of OBRA, pharmacists now have a framework for reinsuring that they are in compliance with regard to counseling and maintaining patient profiles. The tide appears to be moving inevitably toward broadening the scope of counseling as a way of improving patient compliance.

Certainly, the need is clear.

As dedicated health care professionals who care about their patients' well-being, pharmacists possess the skills, training and talent to take a leading role in the new age of patient counseling.

Editor's Note: A booklet summarizing the Schering Report may be obtained by writing the Pharmacy Affairs Department, Schering Laboratories, Kenilworth, NJ 07033.

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A New Approach to Pharmaceutical Care

The MEDiTrust 'PharmaPhone'

David G. Miller, P.D., Executive Director, Maryland Pharmacists Association



Last fall, my wife and I visited Disney's EPCOT Center. I was fascinated with the interactive video screens that allow you to make restaurant reservations or obtain information from an EPCOT employee. With just a press of a button, you can have a face-to-face conversation with someone a mile or more away. Of course, the expense of that technology would never make for a practical application in the real world. Or would it?

Ordering prescription drugs and other medical supplies has taken a new twist for the residents in and around Paquetville, now that MEDiTrust Pharmacy has installed its first "PharmaPhone" in this small town in north-eastern New Brunswick, Canada.

"PharmaPhone" is a kiosk with video and telephone connections. It operates in a similar way to an automatic teller machine (ATM) but allows the customer to see and be seen by pharmacists miles away. A prescription can be scanned by the machine so that the pharmacist can read it and provide advice. The customer's credit card is read through a standard "card swipe" device to charge for the medication and the order is delivered directly to the customer's home by priority courier.

"This is an example of the information highway improving the standard of customer service to a community regardless of size or location and at competitive prices," said Norman Paul, president of MEDiTrust. "It was just over a year ago that Norman Paul approached us with a dream," said John MacDonald, vice president of planning for NBTel, New Brunswick's major supplier of telecommunications. "He wanted to make his mail-order pharmacy more responsive to customer needs and more interactive but was not sure the technology existed. We proved to him that not only was the technology available but could be quickly adapted by Northern Telecom and that NBTel's advanced network could easily handle the communications requirements."

Paquetville's mayor, Louis Monette, also played a big part in getting "PharmaPhone" installed in his town. Until now, residents have had to travel over 30 kilometers to have a prescription filled. Mayor Monette saw a demonstration of the interactive kiosk, realized that it was ideally suited to his community and decided to approach MEDiTrust. The first working kiosk of its kind is now located in "le marche du village," a convenience store, and will be linked to MEDiTrust pharmacists in Saint John.

MEDiTrust operates two super pharmacies under the regulations of the Ontario College of Pharmacists and the New Brunswick Pharmaceutical Society. The facilities are in excess of 20,000 square feet and are devoted exclusively to medication distribution. Through leading edge technology MEDiTrust is capable of delivering over 20,000 prescriptions per day. Although providing patients with predominantly chronic or maintenance medication, MEDiTrust carries and delivers all types of medication including acute care products.

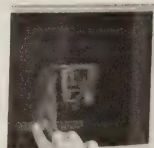
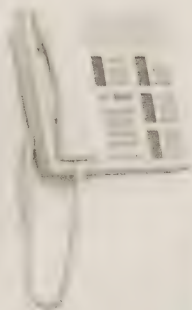
Pharmacy may never be the same.

A photo of the new PharmaPhone appears on the following page.



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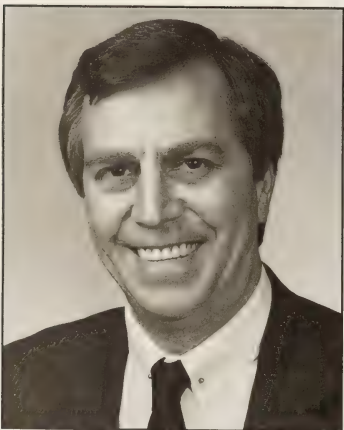
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Patient Counseling

Advising Patients on Benign Prostatic Hyperplasia

Thomas A. Gossell, R.Ph., Ph.D., Dean, Ohio Northern University

J. Richard Wuest, R.Ph., Pharm.D., Professor of Pharmacy, University of Cincinnati



This educational program is made possible through a grant-in-aid from

SEARLE

Benign prostatic hyperplasia (BPH) is defined as an enlargement of the prostate gland that occurs with aging. About 25 percent of males will notice a decrease in the force of their urine stream by age 55, and a 50 percent decrease by age 75.

The Prostate Gland

The prostate gland surrounds the proximal urethra at the base of the bladder. It secretes seminal fluid and may also help protect against urinary tract infections through secretion of the prostatic antibacterial factor (PAF).

Prostate size remains relatively stable prior to puberty. Then the gland begins to enlarge rapidly due to androgen stimulation and reaches adult size of about 20 gm by age 20. Its size remains constant until the mid-40s. It then begins to enlarge again, but at a slower rate. As the tissue enlarges through new cell formation (hyperplasia), it can obstruct the bladder outlet. BPH is not caused by the cells enlarging (hypertrophy); rather, it is by new cell development.

Dihydrotestosterone (DHT) is the principal hormone that regulates both normal and hyperplastic prostate growth. Following puberty, androgen receptors become less sensitive to hormonal influence. This limits additional androgen-stimulated growth. With advancing age this decreased sensitivity is removed. This allows androgen-dependent growth to continue even when there is a decrease in plasma testosterone

concentration.

Testosterone production by the testes is controlled by gonadotropin-releasing hormone (GnRH), also known as luteinizing hormone releasing hormone (LHRH), which is secreted by the hypothalamus. LHRH stimulates the pituitary luteinizing hormone (LH) which, in turn, binds to receptors in the cells of Leydig in the testes where it increases testosterone synthesis. Conversion of testosterone to DHT is catalyzed by the enzyme 5-alpha-reductase.

Benign Prostatic Hyperplasia

Symptoms of BPH are classed as obstructive and irritative (Table 1). The term prostatism describes a number of obstructive and/or irritative symptoms of the micturition process. Generally there is a combination of symptoms.

The major problem associated with BPH is that it obstructs urine outflow from the bladder. The urethra may be blocked partially or completely, creating resistance to outflow of urine. The detrusor muscle of the bladder enlarges. Urinary retention occurs when the muscle can no longer generate sufficient pressure to overcome the increased resistance at the bladder outlet. The degree of bladder obstruction dictates the severity of symptoms. The gland can also enlarge posteriorly to obstruct the colon and cause constipation.

Symptoms worsen over time; some patients appear to improve without surgery or other intervention. Complications associated with BPH

include acute urinary retention, recurrent urinary tract infection, irreversible impairment of bladder secondary to bladder obstruction.

The etiology of BPH is unknown, although several points are established. Functioning testes must be present; eunuchs (castrated males) do not develop BPH. Also, both incidence and prevalence of BPH increase with age.

Symptoms of BPH

Obstructive

Hesitancy
Post-voiding dribbling
Sensation of incomplete bladder emptying
Decreased or interrupted urine stream
Impaired force of urine stream
Double voiding
Strain or push to urinate

Irritative

Frequency
Nocturia
Painful or burning urination
Urgency

Table 1

Prostate size does not always correlate directly with severity of symptoms, and clinical diagnosis of BPH is ordinarily not regarded as an immediate threat to the upper urinary tract or to patient survival. It has been suggested that, for clinical symptoms to appear, there must be an additional acute event, such as prostatic infarction.

Drugs relieve symptoms, but do not modify underlying pathologic changes. Some men with BPH do not seek medical assistance until their symptoms cause significant discomfort or interfere with their quality of life, or their spouse encourages them to do so. These symptoms result from mechanical blockage of the bladder outlet. When irritative symptoms appear in the absence of obstructive

symptoms, physicians suspect a pathologic process other than BPH (e.i., bladder inflammation).

Management Considerations

The goal of therapy is to reduce or eliminate the patient's symptoms. Intervention may also prevent progression of the condition and prevent serious complications.

Patients with BPH should not take drugs that can aggravate their condition. For example, anticholinergics, which lessen detrusor muscle contractions, or sympathomimetics, which block relaxation of the internal sphincter, should be avoided. Medications that can exacerbate the symptoms of BPH include both prescription and OTC drug products such as many cough and cold remedies, hay fever products, decongestants, bronchodilators, and appetite suppressants. Warnings to this effect must appear on labels of OTC products containing antihistamines or sympathomimetics.

Diuretic drugs should be limited as much as possible and preferably taken as a single dose early in the day. Fluid intake, including beverages such as alcohol, coffee, tea, and colas should be restricted after the evening meal to reduce the urge to urinate during the night. Retraining in urinary habits, such as allowing several uninterrupted minutes to urinate, is useful.

Several options need to be considered when treating BPH. They include invasive (instrumental and surgical) and noninvasive (pharmacologic) means.

Pharmacologic Intervention

Treatment of BPH with drugs that reduce the prostate size is now possible. This is good news for those patients who wish to avoid the risks of surgery. Also, there is evidence that pharmacologic intervention can control symptoms in some patients even though they do not affect the

size of the prostate. Drugs can be used for patients who do not have an absolute indication for surgery, and for those who are [poor surgical risks. The goals of pharmacologic intervention are] to reduce adrenergic tone via blockade of adrenergic fibers, and reduce prostate gland size by shutting down hormonal stimulation of the androgenic receptors.

Adrenergic Blockade Smooth muscle forms a significant component of the prostatic stroma (support tissue). The ratio of stroma to epithelium increases to 2.5 times its normal ratio in BPH.

Stimulation of alpha-1 adrenergic receptors initiates smooth muscle contractions in a hyperplastic prostate gland. Their concentration is much greater in the prostate and bladder neck. When activated, they induce urinary retention. Therefore, alpha-1 adrenergic blockade can alleviate symptoms of BPH by relaxing the muscles of the prostate gland, thus decreasing their tone and increasing urinary flow rate. At this point, only terazosin (Hytrin) is FDA-approved for treating the symptoms of BPH.

Phenoxybenzamine (Dibenzylamine) was the first drug used for this purpose. It produces long lasting blockade of both alpha-1 and alpha-2 adrenergic receptors. Although phenoxybenzamine improves urinary flow rates, it also causes significant adverse effects such as vertigo and orthostatic hypotension. It is not used in treating BPH today.

Terazosin is a long-acting selective alpha-1 adrenergic blocker shown to produce significant improvement in obstructive symptoms and urinary flow rates. The drug's long half-life allows for once-daily dosing, which should aid compliance. Adverse effects include dizziness, headache, fatigue, and orthostatic hypotension. The latter can be minimized by administering the drug at bedtime. Although the incidence of terazosin-related hypotension is similar in normotensive and hypertensive patients, blood pressure should be monitored during therapy.

Acetaminophen may be given prophylactically, one-half before terazosin, to lessen the severity of headache. Headaches usually subside spontaneously after several weeks of treatment.

Alpha-1 adrenergic blockers are suited particularly for elderly hypertensive men, since both hypertension and BPH are characteristic at this age.

Hormonal Therapy. Hormone therapy has a single action. It suppresses formation of DHT. It is effective, but clinical utility and patient acceptance are limited by adverse effects, primarily sexual dysfunction. Efficacy is limited because only the glandular epithelium is amenable to hormonal treatment, and this area represents only approximately 30 percent of the prostate gland volume in patients with BPH. Hormonal therapy must also be continuous or the gland will return to its former size.

Luteinizing Hormone-Releasing Hormone. Androgen production can be inhibited by blocking LH release. LHRH analogs, e.g., leuprolide (Lupron) and goserelin (Zoladex), inhibit pituitary release of luteinizing hormone, thus preventing production of testosterone. In addition to reduced prostatic testosterone levels, DHT and 5-alpha-reductase concentrations are also lowered. Unfortunately, in spite of a 95 percent reduction in prostate size in six months, only one-third of men in clinical trials report significant improvement in symptom control. Additionally, more than one-half of the men taking these drugs complain of loss of libido.

Anti-Androgen Therapy Anti-androgen drugs antagonize the action of these hormones at the target-tissue level by competing for binding sites. Anti-androgens reduce prostatic volume, but do not inhibit production of testosterone. Maintenance of testosterone preserves sexual potency, but adverse effects such as nausea, diarrhea, dizziness, and gynecomastia, are

Examples of Therapy for BPH

Invasive Intervention

- * Open prostatectomy, surgical removal of gland.
- * Transurethral resection of the prostate (TURP): most common procedure. Cutting away of hyperplastic tissue.
- * Transurethral incision of the prostate (TUIP): incision made through gland to relieve pressure.
- * Transurethral dilation of the prostate (TUDP): balloon inserted through urethra and tissue compressed
- * Transurethral hyperthermia: tissue destroyed via microwaves
- * Laser destruction: tissue destroyed via laser

Pharmacologic Intervention

- * Alpha-1 adrenergic receptor blockers: terazosin
- * Hormonal therapy
 - LHRH agonists: leuprolide, goserelin, etc.
 - Anti-androgens: flutamide, megestrol, cyproterone, etc.
- * 5-Alpha-reductase inhibitors: finasteride

In addition, behavioral modifications will be instituted, such as regular voiding, restricting fluids after the evening meal, etc.

Table 2

relatively common and bothersome.

Flutamide (Eulexin) inhibits binding of DHT to receptors in the prostate, initiating increased LH and serum testosterone levels. Flutamide is approved only for the treatment of symptomatic prostate cancer when used in combination with an LHRH analog.

Progestational anti-androgens, such as megestrol acetate (Megace) and cyproterone acetate (Androcur), also block DHT receptors and inhibit LH release centrally. Lowered LH release reduces testosterone production which, in turn, reduces serum testosterone concentrations.

5-Alpha-Reductase Inhibitors. Finasteride (Proscar) is the first and presently only 5-alpha-reductase inhibitor available commercially in the U.S. It represents a significant advancement in the hormonal regulation of BPH for men with moderate symptoms.

When 5-alpha-reductase is inhibited, testosterone conversion to DHT is blocked. DHT is the principal and most potent prostatic androgen and stimulus for hyperplastic cell growth and BPH

development. Therefore, inhibiting DHT removes the source of glandular stimulation. By inhibiting only DHT formation, without interfering with testosterone blood levels, adverse effects associated with generalized androgen blockade are minimized. Since intracellular testosterone concentrations are actually increased, sexual dysfunction is minimized.

Daily dosing with finasteride for six months reduces serum DHT by about 60 percent so that by the end of 12 months therapy, prostate size decrease about 20 percent and urinary output increases. DHT concentrations return to normal within 14 days following discontinuance of the drug, and the prostate returns to pretreatment size within four months.

Adverse effects reported in clinical trials to date are related primarily to sexual activity. These include impotence, decreased libido, and reduced volume of ejaculate.

Concluded on page 24....

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Pregnant women should avoid exposure to crushed finasteride tablet powder. While the probability of absorption through the skin is remote, the possibility of absorption through the skin is remote, the possibility of causing abnormalities to the external genitalia of a male fetus exists. These women should avoid contact with semen of males taking finasteride.

Finasteride is metabolized extensively in the liver. Its potential for interaction with the cytochrome P₄₅₀ enzyme system should be considered. The drug is also highly bound to plasma protein. However, significant drug interactions have not been identified.

Advising Patients

Symptomatic patients should be advised to avoid OTC products that have anticholinergic and/or sympathomimetic action. Such products can exacerbate urinary retention and precipitate acute urinary retention in patients whose symptoms are already severe.

It is recommended that men over the age of 50 receive regular prostate examinations. Early symptoms of prostate cancer is the third common cause of cancer-related deaths after age 55. Prostate cancer that is detected and treated early is curable.

Patient Counseling for Hytrin

1. Hytrin is used to treat the symptoms of enlarged prostate, a condition referred to as benign prostatic hyperplasia (BPH). It is also used to treat high blood pressure.
2. Hytrin should be taken with a full glass of water, with or without food. If stomach upset occurs, take it with food.
3. Hytrin may cause you to be drowsy the first few days you take it or when your doctor increases the amount you are taking. If drowsiness occurs, be careful driving or performing hazardous tasks, or drinking alcoholic beverages.
4. Hytrin may cause you to become

lightheaded. Sit or lie down at the first signs. Avoid sudden changes in posture. Be careful going up and down stairs.

5. Take Hytrin as instructed at approximately the same time every day. Do *not* skip a dose or stop taking the medication without asking your doctor.

6. Do *not* take nonprescription (OTC) cough/cold, allergy, sleep aid or diet medications without asking your doctor or pharmacist. They may aggravate the symptoms of BPH.

7. If you miss a dose of Hytrin, take it as soon as possible. But, if it is almost time for your next dose, skip the missed dose and resume your regular schedule. Do *not* take a double dose unless directed by your doctor.

8. Keep this medicine at room temperature, in its original, labeled container, and out of the reach of children. Do *not* keep or use outdated medicine.

9. Possible Side Effects. Most patients experience little or no problems while taking Hytrin. However, be sure to tell your doctor if the following occur: drowsiness, headache, skin rash, nausea, light headedness, fainting, chest pain, unusual swelling or weight gain.

Patient Counseling for Proscar

1. Proscar is used to treat enlarged prostate, a condition referred to as benign prostatic hyperplasia (BPH).
2. Proscar should be taken with a full glass of water, with or without food.
3. Take Proscar as instructed at approximately the same time every day. Do *not* skip a dose or stop taking Proscar without asking your doctor.
4. It may take at least 6 months of treatment to determine if you will respond to Proscar.
5. If you miss a dose of Proscar, take it as soon as possible. But if it is almost time for your next dose, skip the missed dose and resume your regular schedule. Do *not* take a double dose unless directed by your doctor.

6. Do *not* take nonprescription (OTC) cough/cold, allergy, sleep aid or diet medications without asking your doctor or pharmacist. They may aggravate the symptoms of BPH.

7. FOR WOMEN: Crushed Proscar tablets SHOULD *not* be handled by women who are pregnant or who may become pregnant because of the potential risk to a male fetus. Avoid contact with semen of males taking Proscar.

8. Keep this medicine at room temperature, in its original container and out of the reach of children. Do *not* keep or use outdated medicine.

9. Possible Side Effects. Most patients experience little or no problems while taking this medicine. The amount of ejaculate may decrease during treatment with Proscar. This decrease does not interfere with normal sexual function. However, be sure to tell your doctor if you notice a loss of sex drive or become impotent.

Editor's Note: One hour of Maryland State Board of Pharmacy continuing education credit can be earned by completing the continuing education quiz on page 27. Read the instructions at the top of the quiz, fill in the requested information, and then circle the answers to the questions.

A New Legal Precedent for the Duty to Warn

David B. Brushwood, R.Ph., J.D.



The Court of Appeals of Arizona has recently decided a precedent-setting case on the issue of duty to warn. The appellate court reversed a lower court ruling that the defendant pharmacy had no duty to warn either the patient or the physician that prolonged use of prescription drugs dispensed by the pharmacy, or their use in combination, may lead to addiction or adverse side effects. The appellate court ruled that the defendant pharmacy owed the patient a duty of reasonable care, and that the trial court therefore erred in holding as a matter of law that the pharmacy had no duty to warn.

The facts alleged that from 1960 to 1990, the patient's physician had prescribed Doriden and Codeine, and that the defendant pharmacy had filled most of the prescriptions. For approximately ten years, the defendant pharmacy mailed one or more of the allegedly addictive drugs to the patient at his address in another state. The patient allegedly suffered adverse effects from the two drugs being taken over a long period of time, and this litigation ensued.

The patient presented to the court an affidavit from an expert and portions of the American Pharmaceutical Association Standards of practice for the Profession of Pharmacy. That document indicated that the standard of care for a pharmacist includes obligations to advise a patient of the highly addictive nature of a prescribed drug and of the hazards of ingesting two or more drugs that adversely interact with each other. However, the trial court disagreed that a pharmacist has this duty, and it dismissed the case against the pharmacist.

The appellate court, in review of the trial court's ruling, acknowledged that in a number of American jurisdictions appellate courts have ruled that pharmacist have no duty to warn patients about adverse drug effects. In a minority of jurisdictions, courts have ruled to the contrary. The appellate court, referring to the jurisdictions that had rejected an expanded duty for pharmacists, said, "We reject the analysis relied upon in these decisions."

This is the first case to firmly reject the "no duty" rulings of previous courts. In other cases that have held a pharmacist has a duty to warn, the rationale has been based on unique facts, rather than on a principle of law. Because its result is based on law, rather than fact, this case from Arizona is a watershed, and it foreshadows other similar cases in the near future. Legal recognition of the pharmacist's duty to warn is growing steadily, and this recognition extends to prescriptions distributed through the mail.

Many of the earlier legal cases alleging a duty to warn for pharmacists have been discussed in this column. Each of them is factually distinct, and the vast majority of them have resulted in a ruling that pharmacists have no duty to warn patients about the effects of drugs; instead pharmacists have been considered to be mere technicians who have no responsibility beyond that of accurate medication distribution. Holdings such as these have been viewed as disappointing to a profession that is growing in responsibility and attempting to grow in significance with regard to those who provide compensation to providers of health care.

Yet there have been exceptions to the general rule of "no duty," and the exceptional cases that have ruled in favor of a pharmacist duty to warn have been welcomed by people who realize that through legal recognition of expanded responsibilities, pharmacy can grow in prestige and reimbursement.

Most of the cases in the past that have ruled in favor of a pharmacist duty to warn have done so based on special facts that distinguish them from the "no duty" cases. For example, a pharmacist may know that a patient is an alcoholic when a prescription is presented for a drug that interacts with alcohol; or a pharmacist may know that a medication has been prescribed for a length of time that will produce a toxicity; or a patient may tell a pharmacist that she is allergic to a drug that has a known cross-sensitivity with a prescribed drug; or two prescribed drugs may be known to interact with each other. Each of these cases involves special facts known to the pharmacist, which give rise to a duty to warn the patient. In cases such as these, the courts have usually said that a pharmacist has no general duty to warn patients, however the special nature of the specific fact situation makes the case different from most, and therefore the court recognizes a duty to warn.

The recent Arizona case is different because it rules that a pharmacist's duty to warn patients about adverse drug effects arises out of the relationship that pharmacists have with patients, not out of facts that were known to the pharmacist. The Arizona case changes the general rule of pharmacist liability, rather than finding a narrow exception to the rule, as have previous cases that have held that a pharmacist has a duty to warn. The rule of the Arizona case is that pharmacists have a duty to warn patients about adverse effects. The next question is whether the fact that was allegedly not warned of should have been, given the relevant standard of practice. That is a question of fact to be resolved by a jury. This case will now proceed to the jury trial phase for that determination.

Based on: *Lasley v. Shrales Country Club Pharmacy*, 1994 Westlaw 109647 (Ariz. App. April 5, 1994). Copyright 1994, David B. Brushwood. All rights reserved.

About the Author

David Brushwood is Professor of Pharmacy Health Care Administration at the University of Florida. His articles on cases affecting pharmacies and pharmacy are provided as a courtesy to state pharmacist associations. Questions on legal issues affecting Maryland practice should be directed to your legal representative or the Maryland State Board of Pharmacy.

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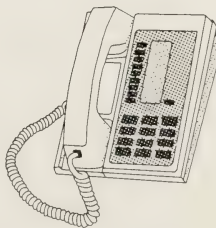
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Continuing Education Quiz

June 1994 -- Benign Prostatic Hyperplasia

This month's questions are taken from the article on topical Rx-to-OTC switch products that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. Members should enclose payment of \$5.00 (non-members \$10.00). The completed quiz for this issue must be received by November 30, 1994. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

Social Security Number _____

Address _____

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1. The muscle in the bladder that enlarges in patients with benign prostatic hypertension is the:
 - a. sphincter muscle.
 - b. pelvic muscle.
 - c. detrusor muscle
 - d. urethral muscle.
2. The principle hormone that regulates both normal and hyperplastic prostate growth is:
 - a. aldosterone.
 - b. dihydrotestosterone.
 - c. methylprednisolone.
 - d. chorionic gonadotropin.
3. Which of the following is least likely to aggravate benign prostate hyperplasia?
 - a. Analgesics
 - b. Decongestants
 - c. Appetite suppressants
 - d. Hay fever remedies
4. The group of antihypertensive drugs that is useful in alleviating the symptoms of benign prostatic hyperplasia is the:
 - a. alpha-1 adrenergic blockers.
 - b. beta-1 adrenergic blockers.
 - c. angiotensin converting enzyme inhibitors.
 - d. thiazide diuretics.
5. The group of drugs referred to in question #4 are effective for this use in benign prostatic hyperplasia because they:
 - a. increase bladder muscle tone.
 - b. increase urine flow.
 - c. relax the muscles in the prostate gland.
 - d. reduce the size of the prostate gland.
6. Which of the following is a member of the group of drugs referred to in question #4?
 - a. Capoten
 - b. Vasotec
 - c. Proscar
 - d. Hytrin
7. Androgen production is most likely to be inhibited by blocking the secretion of which the following?
 - a. Adrenocorticotrophic hormone
 - b. Follicle stimulating hormone
 - c. Human growth hormone
 - d. Luteinizing hormone
8. Finasteride exerts its pharmacological action by inhibiting which of the following enzyme systems?
 - a. Alpha reductase
 - b. Cytochrome
 - c. Monoamine oxidase
 - d. Carbonic anhydrase
9. Which of the following groups should be advised to avoid exposure to crushed finasteride tablet powder?
 - a. Children under 12
 - b. Postmenopausal women
 - c. Impotent males
 - d. Pregnant women
10. Which of the following is classified as an obstructive symptom of benign prostatic hyperplasia?
 - a. Frequent urination
 - b. Hesitancy when urinating
 - c. Nocturia
 - d. Painful urination



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LSD

An Interesting Look at a Different Drug

Carla Showacre, P.D.



The letters LSD come from the German word *lysergsaurediethylamid*. The English translation of that is d-lysergic acid diethylamide. LSD was first synthesized at Sandoz Laboratories in 1938. It is sometimes called LSD-25 because it was the twenty-fifth derivative of lysergic acid that the researchers had synthesized. It can be made from a component of the fungus *Claviceps*. The researchers were looking for chemicals that resembled nikethamide, a chemical producing central nervous system stimulation. Nikethamide has been used as a respiratory stimulant, but its effective dose is close to the dose that may produce convulsions.

On Friday, April 16, 1943, one of the researchers, Albert Hofmann, inadvertently ingested some LSD. In his notebook, he recorded his experiences. He described the visual imagery as kaleidoscopic with vivid colors. His experience lasted about 2 hours. This was the first time LSD *per se* was recognized as being a hallucinogen.

The following Monday he deliberately swallowed 250 mcg to substantiate that his reactions were related to the LSD. Dr. Hofmann noted that LSD was tasteless. He had prepared what he felt would be a small dose. This was actually a substantial dose of LSD and apparently much higher than his first dose. Dr. Hofmann found that the onset of its activity occurred in about 40 minutes. He had a distorted perception of time and objects. People also changed. There was much colorful visual imagery. Even sounds were somehow converted into visions. He also had some out-of-body experiences. The effects of the drug lasted about six hours.

Many of Dr. Hofmann's observations were upheld by future researchers. Visual hallucinations predominate. Only rarely are auditory hallucinations reported. There is an ongoing debate whether LSD produces true hallucinations. The visions seen with LSD typically have some grounding in reality, in objects actually present during the "trip." Many psychologists seem to be partial to defining hallucinations as having no basis in reality.

Other observations from controlled settings indicate that initially people report geometric imagery that is very colorful and has changing forms. Although all colors are reported, as the dose increases, the amount of red seen increases. Later in the trip, people reported more complex imagery. Usually, the subject recognizes that what is seen is not real. This contrasts with schizophrenic hallucinations where the patient usually loses that ability to discriminate.

After an oral dose of 100 to 250 mcg, the subject has an increased heart rate, blood pressure, temperature and respirations. Pupils become dilated. The visual imagery and time deformity usually last from the first through sixth

*The visions seen
with LSD typically
have some
grounding in reality,
in objects actually
present during the
"trip"*

hours. Later, people have insights that vary. At this time, the user is tuned in to those around him.

There are a number of theories to explain the hallucinations of an LSD trip. One is that the hallucinations result from CNS stimulation plus a lack of organization in the reticular modulating system. Another theory suggests that hallucinations result when internal awareness dominates the recognition of the outer world. This theory maintains that memories are regulated by processing of information that flows from the outer world to within the person.

Psychologists seem to agree on the importance of set and setting to the individual using LSD. Typically, a guide leads the initiate and stays with him. Appropriate preparation that offers some direction has been beneficial. For example, Kurland has used LSD to help patients deal with terminal cancer. Much time is spent beforehand examining what the patient wants to derive from the experience. Evidently, when LSD is used to enhance spiritual encounters, the subjects also respond to some psychological preparation and the physical environment.

During the 1960's, LSD was used recreationally by a significant number of people. People started appearing in hospital emergency rooms and clinics having bad trips. How they were handled potentially affected the outcome. The Haight-Ashbury Free Medical Clinic developed a Calm Center where the employees were nonjudgmental and dressed in street clothes. They talked the user down through the remainder of the trip. They reassured him/her that this experience would come to an end. Some other places handled the bad trips or panic reactions differently. The patient was treated with impersonal hostility. Sometimes the stomach was washed. Never a pleasant experience, this was especially difficult in the midst of a bad trip. Since LSD is readily absorbed after oral ingestion, there was also little point to pumping the stomach.

The talkdown is usually sufficient. If it is not, sedation with 25 mg of chlordiazepoxide or 10 mg of diazepam given orally is the next strategy. In the later stages of a bad reaction, it is sometimes necessary to give an antipsychotic by injection. At this point, presumably the patient is in danger and unwilling to take the current drug of choice, according to Smith and Seymour (1985). Hospitalization should be the last resort, but is probably necessary if the antipsychotic must be used.

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What's Your Pharmacoeconomics I.Q.?

Test yourself! Answers at bottom of page.

1. Outpatient prescription medicines account for approximately what percent of total health care spending?
a. 5% b. 10% c. 15% d. 20%
2. How many years of patent life typically remain once a new drug is approved for marketing?
a. 17 b. 10-12 c. 3-5 d. 5-7
3. Which amount is the closest to the actual cost of dispensing a prescription in a full-service pharmacy?
a. \$2.00 b. \$3.35 c. \$6.00 d. \$1.25
4. Out of every ten new drugs marketed, on average, how many achieve sufficient revenue to cover costs and make a profit?
a. 8 b. 2 c. 6 d. 1
5. Considering drug prices and manufacturing wages in the U.S. & Mexico, how long do Mexicans work compared to Americans to pay for Rx drugs?
a. same # hours b. Half as long c. more than twice as long
6. What is the current estimated cost of bringing a new drug to market?
a. \$175 million b. \$359 million c. \$500 million d. \$100 million
7. Which component of health care costs are patients most aware of because they pay out of pocket?
a. physician b. prescription c. hospital d. emergency room
8. What percent of sales, on average, is spent on research by research-intensive pharmaceutical manufacturers?
a. 25 b. 16 c. 8 d. 11
9. Total health care expenditures have risen to almost 13% of GNP since 1960. How have pharmaceutical costs behaved as a % of GNP during that period?
a. risen to 3% b. fallen to 0.5% c. held nearly constant under 1%
10. If pharmaceutical industry profits were eliminated, how much would this reduce total national health care costs?
a. 3% b. 5% c. less than 1% d. 10%

Answers: 1 a. 5%; 2 d. 5-7; 3 c. \$6.00; 4 b. 2; 5 c. more than twice as long; 6 b. \$359 million; 7 b. prescription; 8 b. 16; 9 c. held nearly constant under 1%; 10 c. less than 1%

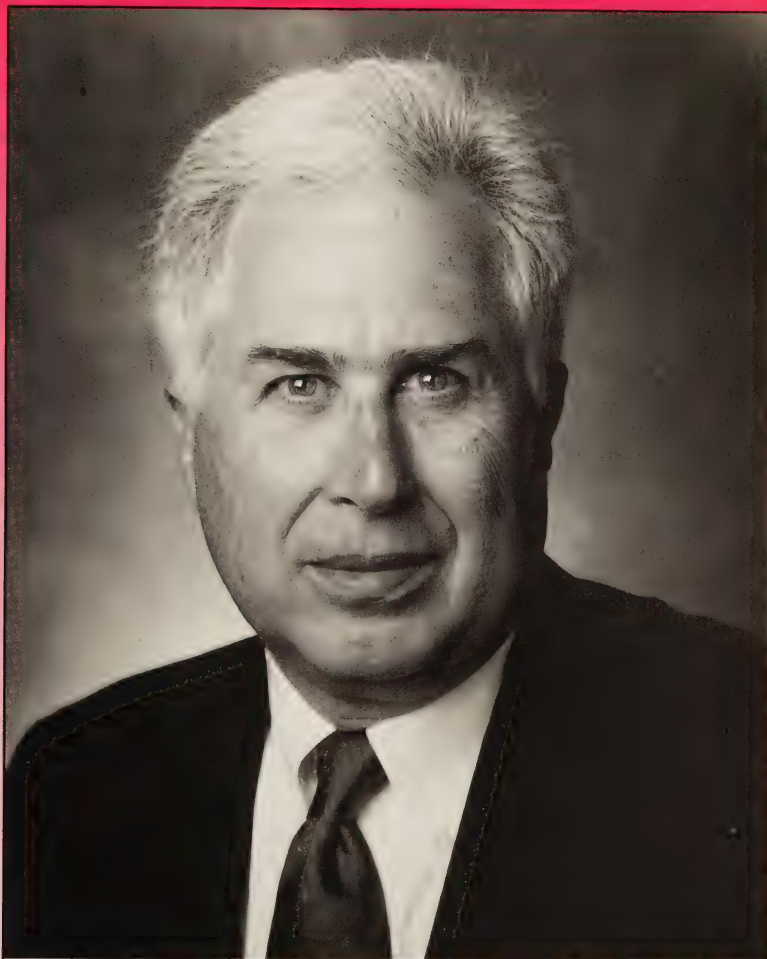
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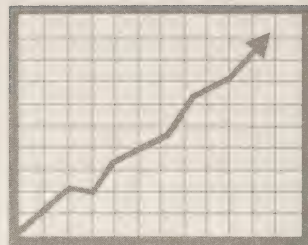
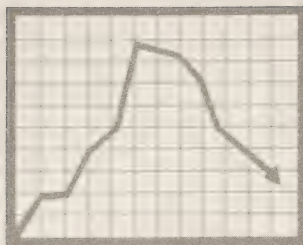
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July, 1994

NO. 7



Arnold L. Davidov
1994-1995 MPhA President



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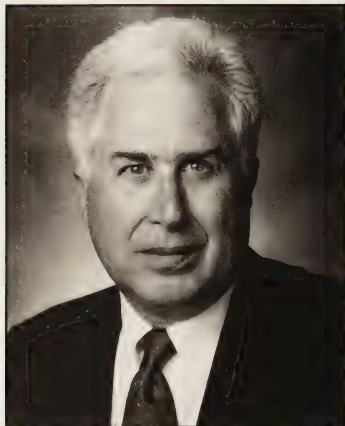
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President's Commentary

Arnold L. Davidov, P.D.



I begin my term as MPhA President before you as a true representative of a pharmacy family. This relationship started in 1924 when my father, Louis Davidov, graduated from the University of Maryland School of Pharmacy. My mother, Betty Davidov, was a confounder with my father of Tuxedo Pharmacy in 1936. Betty is, to this day, a "working woman" in Tuxedo Pharmacy, and was one before the phrase became popular jargon. By the way, my mother is a registered nurse having graduated from the Sinai Hospital School of Nursing. Other family members involved in the pharmacy include my brother, Harold, who shares overall responsibilities with me -- or at least when our mother lets us.

My first involvement with pharmacy association began after Harold and I attended a meeting of the Baltimore Metropolitan Pharmaceutical Association in 1986. The "burning" issue that got me to that meeting was physician dispensing. At this meeting I met this intense, high-energy individual who told me, because this was such a big issue for me, that he would personally go the legislature and have a bill passed to put this practice to an end.

You know what he did? With my help and others, we finally got it passed in 1989. Of course, you know I am talking about the former MPhA Past President Nat Futrel who passed away so tragically just two years ago on the way home from the 1992 MPhA Convention.

Also at that 1986 meeting was Elwin Alpern, who I would get to know much better later on in Association activities. Elwin served a President of the MPhA in 1988-1989 and Nat followed him in 1989-1990. During their era we hired our first full-time lobbyist, Robin Shaivitz and established the Association's Survival Fund to the tune of \$40,000. With the help of David Miller, our Executive Director, these efforts enabled our association to flourish in a very demanding and fast changing environment.

These two men were quite a contrast - Nat, larger than life, stalking, up-front, do it now, nothing too daunting to be overcome. Elwin, quiet, reserved, planning and charting the future, working steadfastly to strengthen the foundations of our Association...as he still works with us today.

What a wonderful team they made!

I will be forever grateful to these two men, for without their support, guidance and inspiration, I would not be writing this as President of the MPhA. As I look back on the past eight years, I realize that I have never stopped working for the Association and, what's even stranger is that I have loved every minute of it. I realize that I represent the end of the "older" order of leadership of the MPhA. And as we pass the mantle of leadership on to younger association members, I want to do every thing possible to prepare them for the challenges that will face our profession in the future.

Concluded on page 27....

The Annual Report of the Board of Pharmacy

Ralph A. Small, Jr., Secretary and Commissioner, Maryland State Board of Pharmacy



In compliance with the provisions as set forth in the Health Occupations Article Section 12-205 of the Annotated Code of Maryland, this report is submitted to the Honorable William Donald Schaefer, Governor of Maryland, the Secretary of Department of Health and Mental Hygiene, Nelson J. Sabatini and to the Maryland Pharmacists Association. This is the ninety-first report to the Governor and Secretary and the seventy-ninth report to the Association. The report covers the activities of the Maryland Board of Pharmacy for the period May 1, 1993 to April 30, 1994. This report is also being submitted to the McKeldin Library of the University of Maryland, the Enoch Pratt Free Library, the Department of Legislative Reference, the Hall of Records and the State Library.

Meetings

During the year the Board held seventeen meetings, five of which were held at the School of Pharmacy of the University of Maryland, for the purpose of conducting examinations for licensure of pharmacists.

Officers and Members

The Board consists of the following officers and commissioners: Steven S. Cohen, President, Ralph Small, Secretary, William E. Adams, Robert J. Kabik, Dorothy Levi, Theodore S. Litwin, Melvin N. Rubin, and George Voxakis. All of the officers and commissioners are registered pharmacists in the State of Maryland with the exception of Mr. Litwin and Mr. Adams who are consumer (public) members of the Board.

Personnel

The staff consists of Roslyn Scheer, Executive Director, Catherine Putz, Pharmacist Compliance Officer, Tamarra Banks, Automation System Specialist, Pamela Bethea, Secretary to the Executive Director, David Oliver, Secretary to the Pharmacist Compliance Officer, Shawnette Fleet, Licensing Secretary, and Doris Thomas, Fiscal Aide.

Examination

The Board conducted examinations for licensure of pharmacists during the year. They were held at the University of Maryland School of Pharmacy on June 22, 23, and 24 1993 and September 28 and 29, 1993.

The applicants who were examined in June of 1993 were licensed in July, 1993 which is in Fiscal Year 1994. There were one hundred eighty-eight applicants for the Board in June 1993. One hundred sixty-one passed both the theoretical and practical portions of the examination and were licensed. Twenty-seven failed the examination.

There were fifty-four applicants for the Board in September, 1993 (Fiscal Year 1994). Thirty-eight passed both the theoretical and practical portions of the examination and were licensed. Sixteen failed the examination.

Data relative to the June 1994 examination will be given in the next Annual Report.

The pharmacist licensure examination is given in two parts consisting: Part I - NABPLEX; and Part II which is comprised of an examination in Laboratory, Maryland Drug Law, and Federal Drug Law.

The NABPLEX and the Federal

Drug Law Exam are obtained from the National Association of Boards of Pharmacy. The Maryland Law Exam and the Laboratory Exam were compiled by members of the Board. The Laboratory Examination requires the compounding of four prescription per applicant. Table 1 shows the number of pharmacists who were licensed by examination during the past ten years.

Year	Number of Pharmacists
1982-1983	116
1983-1984	92
1984-1985	92
1985-1986	109
1986-1987	105
1987-1988	121
1988-1989	135
1989-1990	167
1990-1991	156
1991-1992	149
1992-1993	145
1993-1994	199

Table 1

As in the past, many pharmacists applied for reciprocal licensure in Maryland in order to accept positions with their employers in Maryland.

In all cases, an applicant for reciprocal licensure must appear for a personal interview. The entire Board must act on whether or not to grant licensure to such applicants, who must sign an agreement to comply with Maryland's laws pertaining to drugs and pharmacy.

Table 2 shows the number of pharmacists granted licensure by reciprocity and the number who were certified to be licensed by reciprocity in other states during the past ten years.

This table shows Maryland gained 1,142 pharmacists by reciprocity during the past eleven years.

Permits Issued

As of April 30, 1994, 287 new permits to operate a pharmacy were issued. 116 new permits were issued in Baltimore City. The remaining 171

Year	R ¹	C ²
1983-1984	119	58
1984-1985	148	54
1985-1986	191	70
1986-1987	206	75
1987-1988	197	57
1988-1989	228	86
1989-1990	187	103
1990-1991	212	98
1991-1992	178	86
1992-1993	192	119
1993-1994	190	88
Total	2,048	906

R¹ Pharmacists licensed in Maryland by reciprocity.
C² Pharmacists certified to be licensed by reciprocity in other states.

Table 2

of these permits were issued in the following Maryland counties:

Allegheny	6
Anne Arundel	2
Baltimore	115
Carroll	1
Cecil	5
Charles	5
Dorchester	5
Garrett	5
Howard	8
Montgomery	5
Prince Georges	13
Worcester	3

Of the 280 locations that were issued permits, 10 were name changes. New permits were issued reflecting the changes.

In June, 1987, regulations were promulgated under COMAR, Title 10, Subtitle 34, Chapter 17, allowing waiver of full service requirements for recognized pharmaceutical specialties. As of April 30, 1994, the Board issued twenty-two (22) new pharmacy waiver permits as follows: ten (10) in Baltimore County, four (4) in Carroll County, two (2) in Howard County, two (2) in Montgomery County, three (3) in Prince Georges County, and one (1) in Talbot County.

New permits to manufacture drugs, medicines, toilet articles, dentifrices, or cosmetics as of April 30, 1994 were issued to thirty-one (31) firms.

The Board issued two hundred thirty (233) new permits to distribute prescription drugs as of April 30, 1994.

The total number of establishments licensed through the State of Maryland is 1,219 and the total number of pharmacists is 6,188 as of April 30, 1994.

Legislation

The following bills which affect pharmacy either directly or indirectly were enacted by the 1994 General Assembly. These bills must be signed by the Governor to become effective.

SB 32 and HB 346 - Medical Records Prescription Orders - Clarifies in statute that prescriptions are medical records and that the confidentiality of medical records statutes apply to pharmacists.

HB 262 - Prescriptions-Forgery-Penalties - Makes forging a prescription a felony.

HB 330 - Health Insurance Reform - Extensive corrections of Maryland's health reform act of 1993 (HB 1359). Eliminates pharmacists' cost exclusion from paying an assessment to the Health Care Access and Cost Commission.

HB 452 - CDS Schedule Change-Levoalphacetylmethadol - Moves levoalphacetylmethadol from Schedule I to Schedule II.

HB 1222 - Health Insurance Coverage for Off-Label Uses of Drugs - Prohibits insurers from denying coverage of drugs because the use is not FDA approved. Establishes a board to review drugs.

Cooperative Activities

The Board maintained cooperative activities with the Division of Drug Control, Licensing and Certification, the State Department of Health and Mental Hygiene, the University of Maryland - School of Pharmacy, the



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Maryland Pharmacists Association, the Maryland Society of Hospital Pharmacists, the Maryland Association of Chain Drug Stores, Maryland Society of Consultant Pharmacists, City, County and State Police, the National Association of Boards of Pharmacy, and all Pharmacy Boards and Schools throughout the country.

Disciplinary Activities

The Board of Pharmacy receives complaints from the public concerning problems with the Board's licensees. Other complaints were received from the Division of Drug Control, Medical Assistance Compliance Administration, Licensing and Certification, State of Maryland Courts and other state boards of pharmacy. The wide range of complaints varied in severity. in Table 3 are statistics concerning the types of complaints for the period of May 1993 through April 1994.

Complaint	Number
Expired Prescriptions	5
Freedom of Choice	2
Generic Substitution	5
Mislabeled Prescriptions	5
Incorrect Drug Dispensed	25
Shortages of Controlled Drugs	2
Communication	2
Dispensing Habits of Pharmacist	2
Fraud	2
Pricing	3
Prescription Not Dispensed	3
Advertisement	1
Theft of Drugs	1
Board action by another State	3
Behavior Inconsistent with Professional Standards	9
Total Complaints	70

Table 3

During the period of FY 1994, twenty-six Orders were issued and distributed for public information. These 26 Orders regarding all pharmacists, which included: emergency suspensions (3), suspension (5), suspensions with immediate stay and probation (10), full reinstatement (5), surrender of license (3).

During this period, the Board voted charges for violation of pharmacy law against 32 pharmacists. Twenty-six pharmacist cases have been concluded (included in the above statistics) and six are outstanding. Of these, three pharmacists' licenses are currently suspended on an emergency basis pending final resolution.

The Board has 12 additional outstanding cases from the previous year which have not been concluded. For three of these cases an emergency suspension has been issued and two pharmacists have voluntarily surrendered their license. These pharmacists can not practice. For the other seven cases the Board has voted charges for formal action.

Some pharmacists were convicted of violating more than one statute. Listed below are the types of violations according to the section of 12-313(b) of the Health Occupations Article and the number of pharmacists convicted of each:

- Fraudulently or deceptively uses a license 1
- Provides professional services while:
 - (i) Under the influence of alcohol; or
 - (ii) Using any narcotic or controlled dangerous substance, as defined in Article 27 of the Code, or other drug that is in excess of therapeutic amounts without valid medical indication 5
- Submits a false statement to collect a fee 5
- Willfully makes or files a false report of record as part of practicing pharmacy 6
- Willfully fails to file or record any report that is required by law 4
- Without first having received a written or oral prescription for

- the drug from an authorized prescriber, dispenses any drug for which a prescription is required 9
- Except as provided in §12-511 of this title, unless an authorized prescriber authorizes the refill in the original prescription or by oral order, refills a prescription for any drug for which a prescription is required 3
- Violates any provision §12-603 of this title, which concerns the labeling requirements for prescription medicines 2
- Is professionally, physically, or mentally incompetent 5
- Is convicted of or pleads guilty or nolo contendere to a felony or to a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside 3
- Is disciplined by a licensing or disciplinary authority of any other state or country or convicted or disciplined by a court of any state or country for an act that would be grounds for disciplinary action under the Board's disciplinary statutes 5

Data Processing

Office automation plans are continuing despite delays in equipment arrival and installation. Computerized licensure logs have replaced many of the handwritten journals. Automated licensure functions are now performed directly by the Board staff. Previously these activities were done by a centralized unit. This type of automation in addition to adequate staffing contributed to reducing the daily verification and processing time tasks. The Board will continue implementing the office automation plan and expects to see operational improvements in other areas of operation, such as reconciliation, discipline and compliance.

Finances

SB 655 Health Occupations - Boards - Special Funds which became effective July 1, 1992 required that Board revenues cover all direct and indirect costs of operation of the Board. Board fees were set based on estimates of the numbers of applications and renewals anticipated. The pharmacist biennial license renewal fee was increased from \$50 to \$135 based on regional and national averages of fees charged by other boards of pharmacy. The Board's FY 1992 and FY 1993 revenues exceeded the amount allocated for expenditures in the budget. This surplus has allowed the Board to reduce the pharmacist license renewal fee from \$130 to \$95 beginning with the September 1994 renewal. This will bring the renewal fee paid every two years by pharmacists below regional and national averages.

Financial Statement

The Board of Pharmacy had revenues of \$257,272 in 1992 and \$805,961 in 1993. The Board's budget for 1993 was \$518,290 and is \$515,076 for 1994.

Regulations

During 1993, as required by Law, the Board reviewed all of its regulations. The results of that review are listed below.

The Board promulgated the following regulations, either amended, or new:

10.34.17 - Waiver of Full Service Requirements for Recognized Pharmaceutical Specialties (amended)

The Board has the following amended, new, or repealed regulations in progress:

10.34.02 - Examination for Licensure and Internship Programs (amended)

10.34.03 - Institutional Inpatient Pharmacy Regulations (new)

10.34.07 - Pharmacy Equipment (amended)

10.34.09 - Fees (amended)

10.34.13 - Reinstatement of Expired Licenses for Pharmacists (amended)

10.34.16 - Application Fee (repealed)

10.34.22 - Licensing of Wholesale Prescription Drug Distributors (amended)

10.34.23 - Long Term Care Facilities (new)

Continuing Education

Throughout the year, the Continuing Education Task Force has accepted requests for approval of Continuing Education (C.E.) programs and providers.

A new form has been developed to be included with pharmacist renewal applications. It was used for the first time with the 1993 renewals. Pharmacists renewing as of October 1, 1993 were required to list at least 30 C.E. hours earned during the renewal period. As a result of this requirement to research their files, there was an increased number of pharmacists who requested an extension of their renewal period in order to obtain the minimum of 30 C.E. hours.

The fourth monitoring of C.E. documentation began in February and is still in progress.

Secretary-Treasurer's Message

Wow!! Here it is almost mid-year 1994. Ten years on the Maryland Board of Pharmacy. Where has Bunky Lachman gone? Where has Anthony Padussis gone? Where has Paul Freiman gone? And Steven Cohen, you too will have soon been gone.

Ten, short rapidly changing years. After such a swiftly moving period will I really be relinquishing my role of Secretary of the Board of Pharmacy in search of other pharmacy endeavors? "Yes I am."

During these past years, there have been many changes in the way the Board of Pharmacy operates. Key to the operation of the Board is the self funding mechanism to finance the fiscal aspects of the Board. With legislative oversight, the Board's budget is sufficient to carry out the responsibilities of the Board.

Paramount to the success of the Board is the smooth manner in which the staff of the Board implements the mandates and obligations to serve both the public and the pharmacy community. Roslyn Scheer, Executive Director, works closely with staff to optimize results and plan for the future. I congratulate Catherine Putz, P.D., Tamarra Banks, Pamela Bethea, Shawnette Fleet, David Oliver, Doris Thomas, and Roslyn Scheer on a job well done. As I leave the Board, I feel good about the work you are doing.

Questions frequently arise about the role of the Board of Pharmacy as it relates to the role of Drug Control, headed by Charles Tregoe. The two organizations, both situated in the Department of Health and Mental Hygiene, work closely to regulate pharmacy and drugs in Maryland. In the future, I can envision these two organizations networking to increase the communication involved in solving problems of mutual interest.

To my fellow Board members: Steven Cohen, President; Melvin Rubin elected as Secretary; Bob Kabik; Bill Adams; Dottie Levi; Ted Litwin; and George [RX 001] Voxakis - I wish to thank you for your support and the fine jobs you are doing. It has indeed been a pleasure to work with you, individually and collectively. Again thanks, and keep up the good work.

The Legislature has made changes in the process of how the Maryland Pharmacists Association (MPhA) presents to the Governor a list of candidates from which the Governor

Concluded on page 20....

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A Day in the Life of a Pharmacy Board Member

Melvin Rubin, P.D.



There's a television show called "Commish" with a story line based around a police Commissioner who does not fit the mold of a politician with a long cigar in his mouth, being chauffeured in a limousine. The title character is a blue collar worker who drives his own car, takes part in stakeouts, and pulls his gun to apprehend crooks.

There is a close similarity to the "Commish" and the appointed members of the Maryland State Board of Pharmacy, known as commissioners.

To be nominated by your peers and then appointed by the Governor to the Board of Pharmacy is quite an honor. The position includes policy making, judging the actions of peers, and interacting with local, state, and national figures. The work that is done is important to the public and the profession and comes with a certain amount of authority -- and a long list of duties, meetings, and responsibilities that require a time commitment which goes far beyond the Board's monthly one-day meetings. Even those one-day meetings often run over eight hours.

Pharmacists who want to be considered for nomination to the Board should bear in mind the commitment of time and energy which is required and balance that against just their ability and willingness to serve.

There are six pharmacist members of the Board and two consumer members. While the Maryland Pharmacist Association manages the nomination process of the pharmacist members, the Governor handles appointment of the consumers in a more direct manner. These consumers are expected to participate in almost all areas that touch the Board in addition to their unofficial status of "watch dogs" to see that the pharmacist members apply the primary function, to protect the public, in a fair and open manner.

The majority of the Board's work comes from decisions made during the monthly meetings. These meetings, announced in *The Maryland Register* and usually in the MPhA newsletter, start at 8:30 AM with a public session. At that time, any citizen who wants to attend can discuss issues with the Board as well as listen to Public Agenda items. The public meetings include reports from the Board on proposed legislation and regulations.

After the public session, an Executive Session is immediately started and usually continued until all items are covered.

A typical agenda would include the following areas:

- o Review of the previous meeting's minutes
- o Committee reports: Budget, Licensing, Practice, any special committees
- o Staff Report
- o Questions for the Board
- o Disciplinary Actions: A review of complaints, informal meetings, modification of charges against licensees, reinstatement, proposed suspensions or revocations, among other actions.
- o Review of legislation and regulatory activities.
- o New and old business may well cover a dozen or more areas, and each item is discussed in detail
- o Special business to be discussed

If a licensee has elected to have a full hearing by the Board for allegedly not obeying pharmacy laws, (with court reporter, prosecutor and defender, witnesses, expert witnesses, and evidence being entered), the meeting might run over into a second day.

Since the Board is statutorily required to investigate every complaint by citizens, there are times when members must go on an investigation one or more times and might have to take part in an informal meeting or a pre-hearing conference. These hearings are usually held by a pharmacist and a consumer member, the Executive Director of the Board, and the Pharmacist Compliance Officer. They last anywhere from one to four hours and occur once or twice a month.

Board members are assigned to various areas with which the Board is concerned. These include groups which meet regularly, such as the Pharmacy Rehabilitation Committee and Medical Assistance Pharmacy Liaison Committee, as well as ad-hoc committees formed for a specific purpose and time length.



At the Board's June 15, 1994 meeting, Consumer Member Ted Litwin, Consumer Member Bill Adams, Compliance Officer Cathy Putz, Board staff Pamela Bethea.

Of paramount importance is the way Board members interact with many groups and agencies. In order to carry out their mandates, it is necessary to work with the Division of Drug Control, Licensing and Certification, physician groups, the Board and Commission Steering Committees, as well as many other Department of Health and Mental Hygiene, State, and local personnel and committees, as well as consumer groups. Board of Pharmacy member input in all these areas is essential to our tasks.

The Board has several standing committees which meet an average of four or five times a year plus the time needed to evaluate and complete work brought up at the meetings. The Licensing Committee, which among other responsibilities determines if applicants for the Board exams are qualified to sit for the exam, prepares, and later marks the portions of the exam which are handled locally and certifies the grades and notifies the applicants of their grades. The Practice Committee does the

preliminary work for the full Board meeting in considering areas that need addressing. The Budget Committee has the job of getting the budget ready to be included in the Governor's annual State Budget -- a complex, difficult task requiring work over a several month period, then watching expenditures and income as the year progresses.



From left to right at the Board of Pharmacy's June 15, 1994 Meeting Executive Director Roslyn Scheer, Commissioners Mel Rubin, Bob Kabik, Dorothy Levi and Board Counsel Nancy Tennis.

The better part of five days a year are taken up by Board examinations. Specific tasks such as guiding new regulations that are one page in length as in the case of those concerning pharmacy reference libraries to those like the acute care pharmacy regulations that number more than 15 pages can take a year or more of work.

Each year the Board has the opportunity to introduce new legislation to the General Assembly and also has to follow and react to a host of legislation offered by others that affect the profession. The most hectic time of the year is while the Maryland legislature is in session. Some days Ros Scheer, the Executive Director, has FAX'ed to me more than 10 pages to which I was to respond in as little as an hour to meet a deadline imposed by the legislative process.



Board Commissioner George Voxakis and President Steven Cohen.

To the list of Committees and meetings you might add those that include Board of Pharmacy meetings with other Boards and other areas of the Department or committees formed by the State that require our participation. I'm sure I have missed reporting some of the workload, but think you may have gotten the idea.

Internal needs such as staff development, budget, Board agendas, and meeting protocol are other areas of Board concerns. The President and Secretary are largely accountable for the smooth flow of the Board's work.

What do I dislike the most about being on the Board?.... having to pass judgement on pharmacists that leads to suspension of a license in order to protect the public. What is the most satisfying part?.... seeing pharmacists who had their license suspended work their way back by stages to being able to practice free of any Board imposed restrictions. That may take a year or more and several meetings with the Board to restore privileges. But that time is well spent by Board members.

The purpose of this article is to let licensees, particularly those interested in serving the public and their profession as Board members, know that the being a member of the Board can be satisfying and is important -- but is *rarely* glamorous and *always* time consuming. If you're interested, count on a time commitment of at least two to three full days a month of meetings and work sessions, and probably more. In addition you will wind up with an average of one or two days worth of "homework" (grading up to 200 law exams or researching long term

care regulations which are about 10 pages long, or contacting and summarizing all 49 other state's regulations in a specific area). If you volunteer for or are assigned to a special project add more time.

The Board has a capable staff to do the bulk of the detail work. What I described above is only that work related to policy and policing for the profession. The bulk of the work that it takes to regulate about 8,000 licensees is done by staff and reviewed as needed by Board members.

There can and should be only one reason to want to be a Board of Pharmacy member -- a dedication and desire to serve the public. Fortunately the pharmacists and consumers on the Board now and in previous years all fit that category. Since the Board has no role in the selection of its members other than one vote per pharmacist in the MPhA nomination process, we have to hope that our ranks are annually improved by the infusion of new dedicated pharmacists capable of handling the workload, interacting with all the areas required, and being fair in protecting the public interest.

Oh, and I forgot the good part! We get \$45 a day for each day at an actual meeting and nothing for homework. That's less than two hours of pharmacist pay for a full day's work. At that rate, if I stay on the Board until I'm 98, I might be able to retire. Then I can watch reruns of "Commish" on TV.

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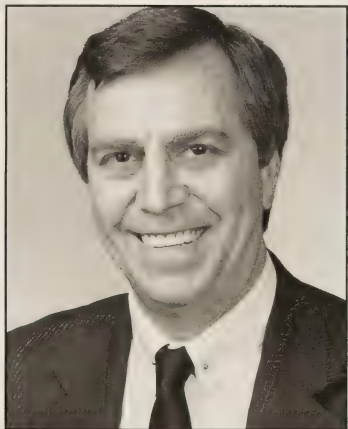
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SEARLE

The availability of products containing hydrocortisone that can be purchased without a prescription has been a major triumph in therapy. The list of topical skin problems that benefit from the use of these products is extensive.

A primary goal of topical hydrocortisone therapy is to maximize its clinical response while minimizing adverse effects. There is no doubt that OTC topical hydrocortisone-containing products confer significant therapeutic activity. Nonetheless, pharmacists have expressed concern about their safety when used without physician supervision for long periods of time.

Background

Hydrocortisone has been available in the U.S. as a prescription drug since 1952. After passage of the Durham Humphrey Amendment to the Pure Food, Drug and Cosmetic Act, which differentiated prescription and OTC drugs in the early 1950s, an effort to switch hydrocortisone to OTC status was denied. FDA felt there was insufficient evidence of safety without medical supervision to warrant nonprescription availability.

Then in 1979, an FDA/OTC advisory panel recommended that hydrocortisone and hydrocortisone acetate (hereafter referred to as hydrocortisone) be categorized as safe and effective for self-medication of itching at concentrations up to 0.5 percent. The panel was provided extensive documentation from numerous scientific studies to support

this recommendation to FDA. Moreover, it was noted that strengths of 1 percent were also used safely in a number of those studies.

FDA agreed with the panel's suggestions and the Agency proposed switching hydrocortisone in concentrations up to 0.5 percent from Rx-only to OTC status. Its decision was based on the presumption that the benefits of OTC availability outweighed the risks of potential misuse. Numerous OTC products were marketed for use as antipruritic, and they received immediate consumer acceptance.

By the end of the first two years of OTC availability, the products were estimated to have saved the American health care system approximately \$600 million. This savings was achieved in reduced physicians' fees, fewer lost work days, and lower medication costs. During the years of OTC marketing hydrocortisone in a maximum strength of 0.5 percent, more than 130 million units were purchased. More recently, FDA has raised the upper limit of OTC products to 1 percent which had been approved in several other countries including Sweden (1985), and Great Britain (1986), without reports of toxicities. Furthermore, it was shown from the experience of consumers and from data reported in clinical trials in the U.S. and elsewhere that hydrocortisone is safe. However, data were also presented to confirm that 0.5 percent-strength products did not provide optimal therapy in all individuals for the conditions for which it was indicated. In seven

controlled studies involving over 4,000 subjects, 1 percent hydrocortisone was shown to be more effective than 0.5 percent. It was, therefore, suggested that the stronger concentrations could benefit a greater number of consumers.

Mechanism of Action

Topically-applied hydrocortisone is believed to act, in part, by binding to steroid receptors within the cytoplasm and/or on the outside of the cell's nuclear membrane. This forms complexes that penetrate the cell nucleus, bind with DNA, and modify transcription of mRNA (messenger RNA - the "road map" of cellular activity). This leads to the synthesis of proteins that have beneficial therapeutic action, such as anti-inflammatory activity in inflamed cells.

Hydrocortisone also modifies the inflammatory process by an action on release and function of chemical mediators of inflammation such as histamine and kinins which stabilize lysosomal membranes. This action suppresses release of the cells' destructive enzymes. There is evidence that corticosteroids induce production of lipocortin, an inhibitor of the enzyme phospholipase A₂. This, in turn, inhibits synthesis of prostaglandins, leukotrienes, and platelet activating factor, all of which are part of the body's inflammatory response to trauma and foreign materials. The therapeutic action of corticosteroids is nonspecific, because it is exhibited against most causes of inflammation, i.e. chemical, mechanical, and immunological.

Some experts state that vasoconstriction is a major component of topical hydrocortisone action. This prevents mobilization of polymorphonuclear leukocytes and monocytes into the area of inflammation. These are two scavenger cell-types that add to the claim that vasoconstriction is not a consistent component of hydrocortisone's action. They state

that significant vasoconstriction is seen in fewer than 10 percent of subjects tested.

Therapeutic Profile

Hydrocortisone is the benchmark against which safety and effectiveness of all topical corticosteroids are measured. It has received the widest recognition, and has been used most extensively in therapy of inflammatory skin disorders. Studies that compare the relative potency of various corticosteroids traditionally rank hydrocortisone as a low-potency anti-inflammatory steroid. At the same time, hydrocortisone ranks high on safety. These properties make it ideal for self-administration.

Some well-known adverse effects associated with more potent topical corticosteroids include iatrogenic (i.e., drug-induced) Cushing's syndrome, appearance of striae (streaks or lines on the skin) if the steroid is used on the face, and corticosteroid dependence. However, these adverse effects have not been documented for hydrocortisone.

When hydrocortisone is applied to normal skin, only 1 percent or less of the drug is absorbed, with only 2.0 percent absorbed through damaged skin. The extent of absorption is dependent, at least in part, on the site of application. It has been demonstrated that absorption of topically applied hydrocortisone, expressed as a ratio where absorption on the forearm equalled 1.0, ranged for 0.14 on the foot arch, 3.5 on the scalp, 6.0 on the forehead, 13 on the jaw angle, and 42 on the scrotum. Even if the improbable "worse case" scenario occurred whereby an individual absorbed the entire contents of a one ounce tube of 1 percent hydrocortisone, only 300mg could reach the systemic circulation. This quantity is only slightly greater than the approved initial oral dose of 240 mg/day for hydrocortisone, and equal to that of hydrocortisone acetate.

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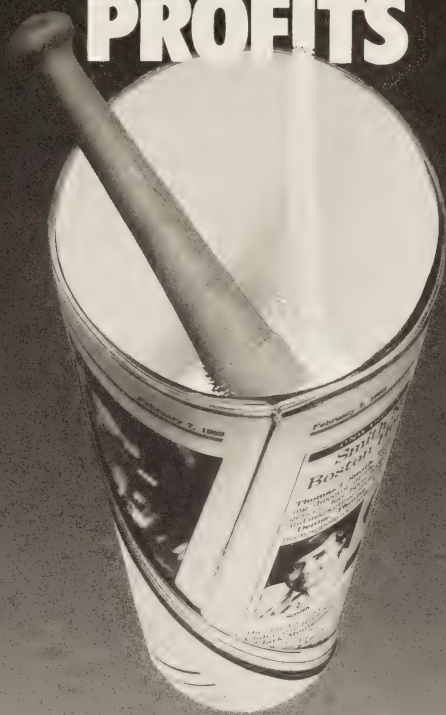
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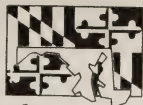
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have severe widespread dermatitis are not candidates for unsupervised hydrocortisone application. Absorption is enhanced in infants. Therefore, hydrocortisone products for OTC use must be labeled to warn against its use in children under 2 years of age. A specific warning against the use of hydrocortisone for diaper rash must also appear on the label.

Absorption may be enhanced tenfold by increasing the skin's humidity and forcing movement of a drug through the skin with an occlusive covering. Tightly-fitting clothing, and ointment-based vehicles may also occlude the skin and enhance absorption.

A summary of adverse reactions for both Rx-and OTC single entity hydrocortisone products reported for the two decades between 1970 and 1989 included 724 accounts. Of these, only 207 were associated with topical use of hydrocortisone in varying strengths of 0.25 percent. Virtually all of the adverse drug

reactions were of a local nature, with contact dermatitis (61 reports), allergic reactions (48 reports), rash (33 reports), application site reactions (23 reports), and pain and pruritus (29 reports) occurring most frequently. In three persons who were hospitalized from using a product containing 0.5 percent hydrocortisone, the product was not used according to instructions. Two of the reactions involved exacerbation of an existing infection. Third included an incidence of bullous erythema multiform (a symptom complex characterized by vivid blisters and lesions which appear suddenly in a symmetrical distribution) that occurred when the product was placed on a scratch and a blister, then occluded with a bandage. If one examines the case studies that report on adverse effects, it can be seen that the reactions described for drug products containing 0.5 percent and 1 percent hydrocortisone are similar qualitatively and quantitatively. The stronger strength does not result in

more hazardous outcomes. Moreover, many, if not most, irritation and sensitization reactions from hydrocortisone products are believed to be caused by the vehicle.

Approved Uses

Hydrocortisone topical products available without a prescription are safe and effective for self-treatment of the symptoms of self-limiting skin disorders. The FDA approved indications are temporary relief of itching associated with minor skin irritations, inflammation and rashes due to eczema, psoriasis, seborrheic dermatitis, poison ivy, poison oak, poison sumac, insect bites, soaps detergents, cosmetics, and jewelry, and for external feminine and anal itching.

To briefly describe these conditions, the term eczema is used interchangeably with dermatitis. They describe mild inflammation (often with redness or discoloration of the skin) of unknown cause.

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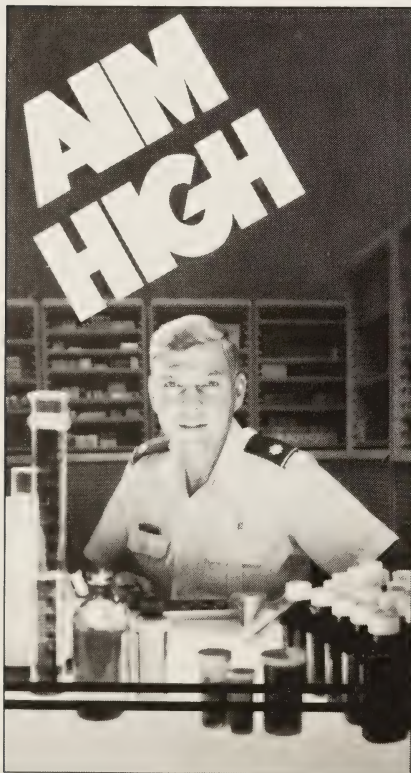
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Containing Hydrocortisone**

Trade Name	Cream	Ointment	Lotion	Aerosol
Bactine Hydrocortisone (Miles)	X			
Caldecort Anti-Itch (Fisons)	X			X
Cortaid (Upjohn)	X	X	X	X
Cortef Feminine Itch (Upjohn)	X			
Cortizone-5 (Thompson Medical)	X	X		
Dermolate Anti-Itch (Schering-Plough)	X			X
Dermtex HC (Pfeiffer)	X			
Gynecort (Combe)	X			
Lanacort (Combe)	X	X		

Table 1

Psoriasis and seborrheic dermatitis involve inflammation and discoloration, and also exhibit scaly patches of skin. They are the result of excessive proliferation of keratin cells and overactive sebaceous glands. Symptoms of mild conditions are self-treatable, but moderate to severe problems require physician intervention and systemic treatment.

Poison ivy, oak and sumac describe a variety of plants (over 50 have been identified) that cause allergic reactions on contact. The reactions result in raised lesions that accumulate fluid. The treatment includes topical hydrocortisone for the symptoms of mild cases and systemic corticosteroids for severe conditions. The same is true for insect bites.

In patients who use hydrocortisone solely to alleviate symptoms, rather than effect a cure, rebound of symptoms upon cessation of therapy is not expected. Reports of relapse often involve patients with dermatologic disorders more severe than the indications for OTC use.

When patients do not obtain the expected relief from OTC hydrocortisone products, or when the symptoms persist or recur after use, physician intervention is necessary. Professional diagnosis and therapy with one of the more potent fluorinated corticosteroids may be required. These drugs penetrate deeper into the dermal areas and increase the possibility of systemic absorption with resulting side effects not seen with topical hydrocortisone.

Counseling Tips

Approval of hydrocortisone for nonprescription use was one of the more significant advancements in self-therapy of many dermatologic conditions. OTC products (Table 1) containing hydrocortisone are safe and effective when used properly. They are best applied in a thin layer, usually 4 to 6 times daily.

Dermatologic afflictions such as insect bites and poison ivy rash are relatively easy to identify. Varying others is more challenging. In fact, for some conditions such as viral

infections (e.g. herpes and warts) and bacterial infections (e.g., acne vulgaris), the condition may be aggravated by topically applied hydrocortisone.

OTC products containing hydrocortisone should not be recommended for treatment of conditions when the cause is uncertain, or when they are long-standing. These require physician diagnosis and treatment.

When recommending hydrocortisone products, the lower-strength products will work satisfactorily for most minor skin afflictions and can be tried first. If they do not provide adequate relief of symptoms within 2 to 3 days, a product containing 1 percent hydrocortisone may provide relief. If the condition does not clear after 7 days of use, physician intervention should be recommended.

The dosage form can make a significant difference in response to the medication. Table 2 summarizes the suitability of various topical formulations based on the affected area.

Cream dosage forms are most often used because of favorable cosmetic acceptance. They are non-greasy, rub in easily, and do not leave a residue. Creams are appropriate for nearly all dermatologic conditions, and can be applied to any area of the body. Lotions are best for chafed areas, and for the scalp or other hairy areas because they spread easily. Sprays are preferred for application to large areas of the skin. Ointments are best used for dry, scaly lesions since they are emollient and retain moisture on the skin providing protection and lubrication.

Satisfactory relief of itching may not be achieved for the first few days after hydrocortisone is applied. Nonetheless, patients should continue to apply the product for 7 days. Another antipruritic remedy containing a local anesthetic or antihistamine, rubbing alcohol, or wet dressings can also be used to control symptoms.

Use of Dosage Forms Based on Clinical Site

Dosage Form	Glabrous non-hairy*	Hairy areas	Palms & soles	Intertriginous areas**
Ointment	XXX		XXX	
Cream	XX	X	XX	XX
Lotion		XX		XX
Solution		XXX		XXX
Aerosol		XXX		XXX
Gel		XX		X

XXX = Preferred dosage form * Glabrous: smooth and bare skin
 XX = Acceptable dosage form ** Intertriginous: skin that rubs
 X = Sometimes used dosage form against other skin

Table 2

Patient Counseling

1. Topical hydrocortisone is used for temporary relief of minor skin irritation, itching and rashes due to eczema, psoriasis, seborrheic dermatitis, poison ivy, oak, or sumac, insect bites, soaps, detergents, cosmetics or jewelry, or, for feminine and anal itching.
2. To properly use this product:
 Wash your hands before and after use.
 Cleanse the skin area with soap and water and pat dry each time you are ready to apply this medicine, unless directed otherwise by your doctor.
 Only the medicine that is actually touching the skin will work. A thick layer is not more effective than a thin layer.

Creams, Ointments and Lotions:

Apply a small amount of the medicine to the affected area and spread lightly.

Lotions and Aerosols: Shake the container well before applying the medicine. This product is for external use on the skin only. *Do not* apply it into or near your eyes or mouth.

Aerosols: Hold the container straight up, about 6 to 8 inches from the affected skin area and spray for 2 to 3 seconds.

3. This product is for external use on the skin only. *Do not* apply it into or near your eyes or mouth.
4. *Do not* apply other creams, lotions or cosmetics on top of our underneath this medicine.
5. *Do not* bandage the area unless directed by your doctor.
6. If your condition persists or worsens, or if you have a constant irritation, such as burning or itching that was not present before you started this medicine, call your doctor.
7. *Do not* use more often or longer than recommended on the label.
8. Read all labels before using this product. If you have any questions, ask your doctor or pharmacist.
9. Keep all medicines out of the reach of children and *do not* keep or use outdated medicines.

Adapted from the Pharmex PALs (patient advisory leaflets). For more information, call 1-800-233-0585.

To earn continuing education credit for this article, please complete and return the Continuing Education Quiz on page 21. This one-credit hour article is only \$5 for MPhA members (\$10 for non-members). Allow six to eight weeks for your quiz to be processed and a certificate mailed.

Board Annual Report

Continued from page 9.

may select a pharmacist to serve on the Board of Pharmacy. As reported by MPhA President Howard Schiff, P.D., MPhA and its nominating committee worked diligently in the past to ensure that all facets of the profession were represented. Usually, the first name on the list presented to the Governor was the Association's preferred candidate. With the change in how this list is derived, the list developed may be determined by a popularity contest.

Ultimately, the appointment to the Board is made by the Governor. The Governor can appoint whomever he pleases. However, the Governor may consider tradition and continuity of the Board in his selection. Changes bring apprehension, but I feel confident about the appointment process.

In closing, I wish to thank former Governor Hughes and Governor Schaefer for appointments to the Board. It has been a distinguished time in my career to serve the citizens of Maryland. Additionally, I wish to thank the pharmacy community for all your help and support.

Editor's Note: This written report was submitted by the Maryland State Board of Pharmacy to the Maryland Pharmacists Association and presented at the 112th Annual Convention, House of Delegates Meeting on Monday, June 20, 1994.

Continuing Education

Continuing Education Quiz

July 1994 -- Hydrocortisone

This month's questions are taken from the article on hydrocortisone products that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. Members should enclose payment of \$5.00 (non-members \$10.00). The completed quiz for this issue must be received by December 31, 1994. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

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A. FDA originally placed topical hydrocortisone in the Rx-only status because:

1. there was no way to approve OTC drugs when it was introduced.
2. there was insufficient evidence of safety for its use without medical supervision.
3. there was evidence that it was too toxic when used for long periods of time.
4. there were no conditions for its use

B. Hydrocortisone is best described as being a:

1. low-potency steroid.
2. intermediate-potency steroid.
3. high-potency steroid.
4. ultra high-potency steroid.

C. When switched to OTC status, the original upper limit for OTC topical products was:

1. 0.1 percent
2. 0.25 percent
3. 0.5 percent
4. 1 percent

D. FDA has approved marketing of OTC topical hydrocortisone products for which of the following indications?

1. Bleeding
2. Infections
3. Itching
4. Pain

E. All of the following are believed to be part of the action of topical hydrocortisone EXCEPT:

1. modifying transcription of mRNA.
2. decreasing the release of histamine.
3. suppressing the release of destructive enzymes.
4. increasing prostaglandin synthesis.

F. The term iatrogenic refers to adverse effects that:

1. are drug-induced.
2. affect developing fetuses.
3. are psychosomatic.
4. have no symptoms.

G. Which of the following dosage forms is best for use on chafed areas, the scalp and other hairy areas?

1. Cream
2. Lotion
3. Ointment
4. Salve

H. OTC topical hydrocortisone products must contain a warning against their use for:

1. anal itching
2. diaper rash
3. eczema
4. seborrheic dermatitis

I. The type of scavenger cell that adds to the inflammatory response is the:

1. platelet
2. erythrocyte
3. leukocyte
4. thrombocyte

J. Which of the following is appropriate condition for recommending the use of an OTC topical hydrocortisone product?

1. Herpes
2. Warts
3. Acne vulgaris
4. Poison sumac

WHAT'S COOL AND WHAT'S NOT

In order to guarantee product potency through the manufacturer's labeled expiration date, a product must be stored and packaged according to label specifications. The USP Practitioners' Reporting NetworkSM (USP PRNSM) has received reports from practitioners confused about storage requirements. Practitioners have expressed concern about products appearing discolored, powdered, wet, or crystallized; having an unusual smell; or changing in consistency.

Consider the following: The label of Sulfacetamide Sodium Ophthalmic Solution USP, 10%, states that it should be stored in a cool place between 46° F and 59° F (8°–15° C). Practically speaking, where would the product be stored in pharmacies, hospitals, nursing homes, and patients' homes? Room temperature is generally 59–86° F and refrigerator temperature is generally 36°–46° F (2°–8° C).

STORAGE AND EXPIRATION DATES

The stability parameters of a drug dosage form can be influenced by environmental conditions of storage (temperature, light, air, and humidity). Required storage conditions must be included in the labeling of all Pharmacopeial articles and should be observed throughout the distribution of the article. Strict adherence to the storage requirements specified in the product labeling will help ensure product potency and stability through to the manufacturer's labeled expiration date. The manufacturer's expiration date only applies if these storage requirements are met from the time the product leaves the manufacturer through its handling by the dispenser or seller to the consumer. Ideally, the pharmacy's labeling, which indicates proper storage conditions for the consumer, should be reinforced during patient counseling. However, it is recognized that proper control beyond the dispenser or seller is difficult.

STORAGE DEFINITIONS

In some USP monographs, there are specific directions for stating the temperature at which Pharmacopeial articles shall be stored. For example, stability data indicate that storage at a lower or a higher temperature produces undesirable results. These directions apply except where the label on an article specifies a different storage temperature on the basis of stability studies for that particular formulation. The following are storage definitions, as defined in the *General Notices* section of the *USP XXII–NF XVII*, for recommended conditions commonly specified on product labels.

- **Freezer**—A place in which the temperature is maintained thermostatically between –20° C and –10° C (–4° F and –14° F).
- **Cold**—Any temperature not exceeding 8° C (46° F). A refrigerator is a cold place in which the temperature is maintained thermostatically between 2° C and 8° C (36°–46° F).
- **Cool**—Any temperature between 8° C and 15° C (46°–59° F). An article that requires cool storage, alternatively may be stored in a refrigerator, unless otherwise specified by the individual USP monograph.
- **Room Temperature**—The temperature prevailing in a working area.
- **Controlled Room Temperature**—A temperature maintained thermostatically that encompasses the usual and customary working environment of 20° C to 25° C (68°–77° F) that allows for brief deviations between 15° C and 30° C (59°–86° F) that are experienced in pharmacies, hospitals, and warehouses. Articles may be labeled for storage at "controlled room temperature" or at "up to 25°", or other wording. An article for which storage at *Controlled room temperature* is directed may, alternatively, be stored in a cool place, unless otherwise specified in the individual monograph or on the label. (See the entire revised definition of *Controlled Room Temperature* in the *Ninth Supplement to USP XXII–NF XVII*.)
- **Warm**—Any temperature between 30° C and 40° C (86°–104° F).
- **Excessive Heat**—Any temperature above 40° C (104° F).
- **Protection from Freezing**—Where, in addition to the risk of breakage of the container, freezing subjects an article to loss of strength or potency, or to destructive alteration of its characteristics, the container label must bear an appropriate instruction to protect the article from freezing.

WHAT'S COOL ON THE INTERNATIONAL FRONT?

The International Conference on Harmonization (ICH) is developing stability standards guidelines. The ICH Quality Working Group is composed of regulatory authorities and industrial organizations of the United States, Japan, and Europe working towards guidelines to be implemented by manufacturers. According to these guidelines, manufacturers, when conducting "real time" product stability studies, will use actual packaging and storage conditions according to the climatic zone in which the product will be marketed. Real-time storage testing would determine the product storage warnings and assign expiration dates to be adopted in its labeling. Of course, they would allow for expected occasional excursions from those conditions. A product labeled for storage up to 25° C (77° F) and a specific expiration date should remain stable and potent through that date if kept at a temperature no higher than 25° C and at a relative humidity similar to the climatic zone for which its expiration date was determined.

The four worldwide Climatic Zones recognized by ICH are based on observed temperatures and relative humidities, both outside and inside rooms, from which mean temperatures and average humidity values are calculated. Zone I, Temperate—includes the United Kingdom, Northern Europe, Canada, and Russia. Zone II, Mediterranean or Subtropical—includes the United States, Japan, and Southern Europe. Zone III, Hot and Dry—includes Australia, Argentina, and Egypt. Zone IV, Hot and Humid—includes Brazil, Ghana, Indonesia, Nicaragua, and the Philippines.

To report problems with drug products or for further information, call the USP Practitioners' Reporting NetworkSM at 1-800-4-USP PRN.

Controlled Substance Diversion

David B. Brushwood, R.Ph., J.D.



A recent Illinois opinion reports on a case in which two pharmacists, who jointly owned a pharmacy, were disciplined for a shortage of controlled substances caused by employee theft.

Pharmacist A and Pharmacist B each owned a 50% share of the corporation that operated the pharmacy. Pharmacist A was registered as Pharmacist-in-Charge. He ordered the prescription drugs and was responsible for security at the pharmacy. He admitted that he did not conduct or request an audit of the inventory after he fired the employee who was caught stealing controlled substances. Pharmacist B worked part time as a pharmacist at the pharmacy. He ordered the cigarettes, sundries, and non-prescription drugs.

The Illinois Department of Professional Regulation suspended Pharmacist A's license for five years and fined him \$2,000. The Department suspended Pharmacist B's license for three years and fined him \$1,500. Both pharmacists appealed.

On appeal, the court noted that Pharmacist B had been disciplined under a law that states "maintenance of security provisions are the dual responsibility of the pharmacist-in-charge and the owner of the pharmacy." The Department had interpreted the term "owner" to include Pharmacist B, based on his 50% share of the corporation. But the court held that the owner of the pharmacy was actually the corporation. A corporation is a distinct legal entity and a shareholder is not an owner of corporate property. The court reversed the Department's finding as to Pharmacist B, and vacated his fine and suspension.

The basis of pharmacist A's appeal was that the penalty imposed by the Department was abuse of discretion. The court noted the legal standard that an agency abuses its discretion when it acts arbitrarily and capriciously or when it imposes an overly harsh sanction in view of mitigating circumstances. The court observed that a hearing officer had recommended a much lighter penalty (30 months suspension, no fine), which the Department rejected without explanation. Therefore, the court vacated Pharmacist A's fine and suspension and remanded the case to the Department for reconsideration and review of the hearing officer's recommendations.

Based on: *Weiner v. Department of Professional Regulation*, 1994 Westlaw 195414 (May 19, 1994). Copyright 1994, David B. Brushwood. All Rights Reserved.

About the Author

David Brushwood is Professor of Pharmacy Health Care Administration at the University of Florida. His articles on cases affecting pharmacies and pharmacy are provided as a courtesy to state pharmacist associations. Questions on legal issues affecting Maryland practice should be directed to your legal representative or the Maryland State Board of Pharmacy.

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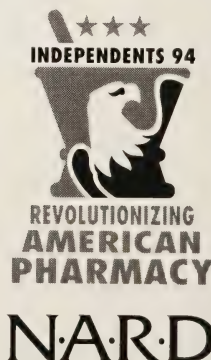
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Instatement of Pharmaceutical Care

Aatif Sheikh, Pharmacy Student, UMB School of Pharmacy

This article is the fifth in a series written by pharmacy students in the first course of the new entry-level Pharm D program at the University of Maryland School of Pharmacy, PHAR 516 (Pharmacy Practice and Education) is an introductory course which exposes the students to pharmacy practice, pharmaceutical sciences, ethics, communication, and critical thinking. One of the class assignments was to write a critical evaluation on one of three topics: pharmaceutical care, pharmacy technicians, or mail-order pharmacy. This course was developed by MPhA Past President Ilene Zuckerman with the assistance of MPhA member and graduate student Diane McNalley.

In recent years, the issue of pharmaceutical care has risen to the forefront in the profession of pharmacy. Although many practitioners agree that pharmaceutical care is the wave of the future, few are clear on what exactly needs to be done to make pharmaceutical care an actuality. Three things which need to be addressed before pharmaceutical care can become reality are making the pharmacist and patient familiar with the ideals of pharmaceutical care, payment of the pharmacist for the services they tender under pharmaceutical care, and the difficulty of implementing pharmaceutical care due to environmental barriers in pharmacy practice.

Many pharmacists want to instate pharmaceutical care into their practice but are unsure of what exactly is involved. The first thing they must do is find out what exactly pharmaceutical care is. Most health care professionals have heard of pharmaceutical care but have only a vague idea of what it entails. Pharmaceutical care is defined as the responsible provision of drug therapy by a pharmacist for the purpose of achieving specific outcomes that improve a patient's quality of life.¹ The activities involved in pharmaceutical care are: directing appropriate, safe, cost-effective drug therapy, identifying and preventing potential drug-therapy problems, resolving actual drug-related problems, and providing drug therapy.^{2,3} Although a pharmacist may know all this, they are not usually prepared to go out and provide pharmaceutical care to their patients. For many years, pharmacists have been involved in dispensing the prescription with almost no contact with the patient. Pharmaceutical care will lead the pharmacist into a more direct contact role with the patient. This means that the pharmacist will need the necessary training to effectively communicate with the patient. Many patients are uncomfortable discussing medical problems with the pharmacist. It becomes the pharmacist's duty to recognize that the patient is uncomfortable and then to put the patient at ease. Then the health professional needs to ask effective questions not only to determine what the actual problem is but also to give the patient confidence that they are speaking to someone who has the knowledge and ability to help them. Also, the pharmacist needs to be trained in how to effectively administer the pharmaceutical care process. This should involve training in establishing the pharmacist-patient relationship, collecting, synthesizing, and interpreting the relevant information, listing and ranking the patient drug-related problems, establishing the desired pharmacotherapeutic outcome for each drug related problem, determine feasible pharmacotherapeutic alternatives, choosing a pharmacotherapeutic solution, individualizing the therapeutic regimen, designing a therapeutic drug monitoring plan, and following up on individual patients to measure the success of the therapy.³ Some schools have begun to offer correspondence courses so that pharmacists, which are out of school, may attain these skills.

Patients also need to be educated so that they may feel comfortable with the pharmaceutical care process. Many retail pharmacies offer a speakers bureau so that the community can request that a pharmacist come out and give presentations. If the pharmacist were to disseminate information about

pharmaceutical care at these presentations it would help to make the patient more aware that pharmacies provide these as part of their regular services. Also, many patients are unaware that the pharmacist has the expertise to counsel them. Many patients have the view that the pharmacist is a "pill pusher" and nothing more. Most patients go to a retail pharmacy where they have no contact with the pharmacist. This causes many patients to be hesitant about asking for the pharmacist because they perceive that the pharmacist is too busy and would consider them an interruption instead of a fundamental part of the pharmacist's work. When a patient comes to the pharmacy, it would be helpful to provide the patient with a medication leaflet which contains information about the drug. Since many patients do not have a scientific background, providing a computer generated leaflet with the patient's name, physician's name, directions on how to take the medication, and common side effects of the drug would not make the patient more comfortable but also would provide the patient with information in laymen's terms.



MPhA PEP Scholarship Winners!

Ngoc Khanh Nguyen, Rodney Taylor and Rhea del Rosario received \$500 scholarships from MPhA in June.

Another factor which needs to be addressed so that pharmaceutical care may be implemented is how pharmacists will charge patients for services. Roger Klotz, a clinical pharmacist who teaches other pharmacists how to get paid for the non-dispensing work they do explains, "Pharmacists say, 'I can't charge my patients if I didn't give them any medication.' That's the wrong attitude. Pharmacists need to be confident. They have to realize that they bring value, knowledge, and skill that benefit patients significantly." Klotz recommends four steps to obtain reimbursement for cognitive services. A pharmacist should get a statement of "medical necessity" confirming that the patient needs the pharmacist's intervention as part of their therapy. The pharmacist should then generate a signed report to show that they stand by their recommendations. The pharmacist should also send a signed copy to the physician for the patients file. The pharmacist should then sent the insurance

company a copy of the physician's request, the pharmacist's documentation, and the pharmacist's invoice.⁴ In this way, the pharmacist has documentation for the service that were provided.

Many patients also do not realize the services which pharmacists provide. As pharmacists continue to strive for the goals of pharmaceutical care, patients must be educated about the services which the pharmacist provides. Patients must realize that preparing medication, screening for errors in prescriptions, identifying potential drug interactions, monitoring the client's progress, and performing administrative duties are important cognitive tasks which the pharmacists must perform in order to provide the patient with pharmaceutical care. With time, the patient will be willing to pay the pharmacist for cognitive services as they do for physicians.

A third factor which needs to be addressed is environmental barriers. In the past, pharmacists have been placed behind glass barriers and have been behind raised desks. As pharmaceutical care has become the model for pharmacies, many businesses have created areas where the pharmacist and patient may go to discuss any problems the patient may be having with their drug therapy. Also, it may be helpful to provide patients with a waiting area which contains chairs and hot beverages so that patients may relax while they wait for the pharmacist. Since the patient would be more comfortable, they may be more willing to open up to the pharmacist.

In conclusion, by overcoming the environmental barriers, by determining a way in which pharmacists may be paid for their cognitive services, and by familiarizing the pharmacist and patient with the ideals of pharmaceutical care will help to provide an ideal environment for pharmaceutical care.

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President's Commentary

Concluded from page 4.

I have, with the Board's approval, already started to implement my ideas. We will start with a Board of Trustees' retreat in September. At this retreat, we will welcome the new trustees and together develop leadership skills to make us a more effective and cohesive Association. I also plan to merge the Legislative Committee and the Third Party Committee into a Legislative and Health Care Policy Committee.

I want MPhA to be out front and pro-active instead of reacting to changes in the health care delivery system. I foresee as an integral part of the new health care alliances that are being formed by hospitals in this area. I want us to be players in this new format, not outsiders as we are presently in the HMO's settings. I want the profession to survive and I will do everything in my power to assure that it does.

We have to look forward, change our thinking. What's behind us is over. It was good for most of us, but it is over.

It is on to a new and more challenging era. I'm not discouraged! I'm energized! I'm looking forward to the challenge and I hope that my involvement and leadership will enable us to flourish in the new environment.

I plan during the coming year to attend as many local association meetings around the state as possible. I want to bring our membership together.

In closing this, my first message to you as MPhA President, I want to tell you that what I cherish most from my involvement with the MPhA are the friendships that have developed and grown with all of you. I especially appreciate those relationships with Ellen, Jim, Ernie, Howard, Nick, David, Maribeth, and our own Mountain Man, Jerry. I hope that I will have the same opportunity to at least begin a relationship with each of you during my term as President.

I thank all of you who have helped me grow and develop into someone I truly enjoy being. Please remember, the success of our Association depends on everyone putting their efforts together for our success.

Thank You!!!

Editor's Note: The text for President Davidov's "Commentary" is derived from his Installation Address during the 112th Annual Convention, June 21, 1994, in Ocean City, Maryland.

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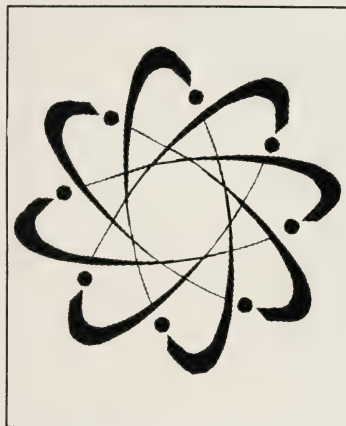
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MPA

A Career in Nuclear Pharmacy

Geoff Christ, MPhA Extern



Nuclear pharmacy is the preparation and distribution of time critical radiopharmaceuticals. Most of the agents prepared by a nuclear pharmacist are diagnostic agents. They are used to test organ function, perfusion, and to detect abnormalities. The agents can be used on such organs as: heart, lung, kidney, liver, and brain. Some other duties of a nuclear pharmacist include: preparation of Iodine 131 therapy for thyroid cancer, tagging white blood cells with radiation for abscess detection, quality assurance of radiopharmaceuticals, clinical information for accounts, and account relations. After two years in the field a nuclear pharmacist can sit for board certification in nuclear pharmacy exam. Nuclear pharmacy was the first specialty recognized by the Board of Pharmaceutical Specialties.

I became involved with nuclear pharmacy by completing a company sponsored summer internship for three months. The internship was at the Syncor location in Timonium, Maryland. After I completed my summer internship I was offered a position as a part time employee. I had extensive experience in many areas of pharmacy practice but immediately fell in love with nuclear pharmacy. Some of the aspects I liked were: being able to specialize in the field of pharmacy, working for a large company, the hours of operation, the extensive clinical activities, and the challenge of entering an area of pharmacy practice that is new to him. Soon I will face another challenge, opening a new location.

The first task that must be completed in opening a nuclear pharmacy is finding a location. The lab must be centrally located to perspective accounts. The accounts serviced by Syncor are mostly hospitals and a few private physician's offices. Once a space is leased modifications have to be made in order to accommodate a nuclear pharmacy. These physical alterations can take up to thirty days to complete. When a new nuclear pharmacy is opened regular pharmacy licensure is required. In addition to this, NRC (Nuclear Regulatory Commission) licenses have to be obtained. Obtaining NRC licenses tends to be a long and pain staking process. Once these licenses are obtained the pharmacy can legally begin operating. This means that radioactive materials can be ordered and stocked by the pharmacy. Obviously, in order to begin operating a good staff must be hired. The staff of a typical Syncor pharmacy consists of pharmacists, manager, CSA's receptionists and sales associates.

Pharmacists are essential to the operation of any pharmacy. In order to become a nuclear pharmacist one must be licensed by the Board of Pharmacy in the state the pharmacy is in. Also a pharmacist must be an authorized user of radiopharmaceuticals. This certification requires 30 credit hours of didactic classroom work and 480 hours of practical experience. Syncor provides the opportunity to get the necessary credits and practical experience.

Customer Service Associates (CSA's) are also vital to the operation of the pharmacy. Their job is very important for two reasons: 1. time is critical in the delivery of radiopharmaceuticals. 2. special training is required to deliver these pharmaceutical. The CSA's require specialized training in addition to a clean driving record. This training consists mostly of DOT (Department of

Geoff Christ, MPhA extern for April, has taken a job with Syncor International Corporation as a nuclear pharmacist. He will be taking part in the opening of a new facility in Seaford, Delaware. Opening a new pharmacy is a challenge enough but opening a nuclear pharmacy poses different challenges in addition to those encountered in opening a regular pharmacy.

Transportation) regulations. A CSA is not allowed to deliver until he passes all written tests. The manager supervised the activities of the location. He/she is also in charge of account relations, employee evaluations, and is in constant contact with the corporate offices.

Opening a new pharmacy is quite an undertaking in itself but opening a nuclear pharmacy is an even bigger undertaking. It sounds like the perfect job for an eager young graduate to participate in. I will be leaving July 1 to begin preparations for the opening of the new location. On July 11 I take off for authorized user training at the company headquarters in Chatsworth, California.

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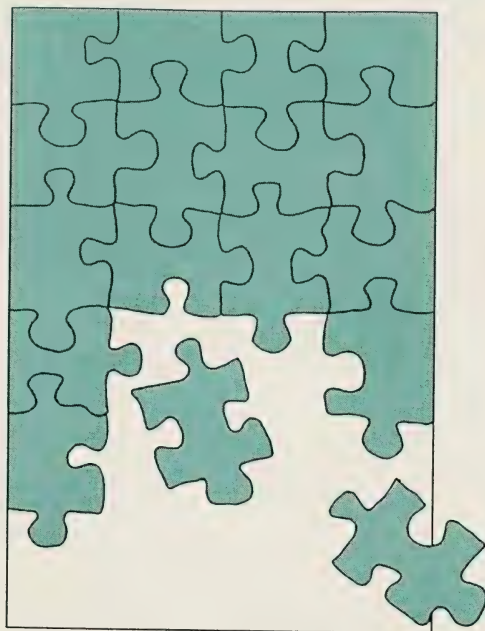
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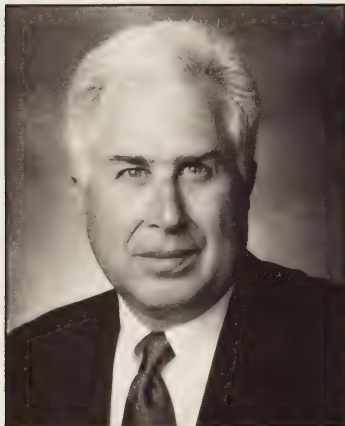
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President's Commentary

Arnold Davidov, P.D., 1994-1995 MPhA President



"Just for once, why can't they all just work together?"

How many times have you said this about our national pharmacy organizations? How many times have you shrugged in resignation or snorted in disgust at the petty squabbling and posturing between who did what for whom or who is claiming credit for the latest "pharmacy victory."

In a profession as diverse as ours, it sometimes seems impossible for our associations to effectively represent the interests of each of our practice segments. For example, can any one organization identify and balance the priorities of our community pharmacists with those of our consultant pharmacists.... or hospital pharmacists.... or home infusion pharmacists.... or even our students? One solution, and one that has proven to be a double edged sword for pharmacy, is to have each practice specialty form its own organization with its own agenda.

While there is no question that an organization comprised of members with like practices and experiences is often more effective in moving forward with the goals of that group, there is also no question that that same organization cannot be as effective in dealing with problems that exceed the scope of their practices. Just as a group of radiologists couldn't profess to know the best thing for internists, we can't expect to have our managed care pharmacists know the best thing for chain employees, or independent owners, or hospital directors. And frankly, I don't think they could.

One thing we must avoid *at all costs* is to have divisiveness among Maryland pharmacists or their society, association, or group. We cannot allow ourselves the luxury of fighting amongst or against each other. We have too many external enemies without adding on ones from inside.

While I don't proclaim to have a magic answer for this situation, I can do one thing as President of MPhA. And that is to make sure that our Board, our Committees, and the issues we tackle together have the greatest amount of input, consideration, and debate from all segments of pharmacy practice. Sometimes our priorities will exactly agree with those of a segment of pharmacy. Sometimes they won't. In either case, though, our Association must do what is best for our members and for the future of our profession.

What ever happens, I don't want to hear you sigh in resignation and say "If only MPhA could work with...."

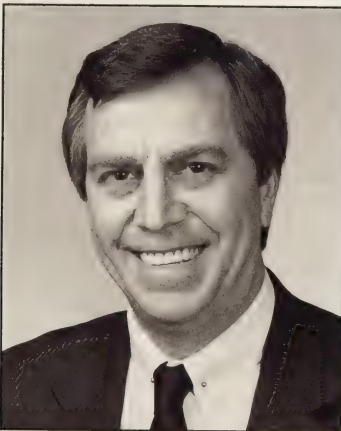
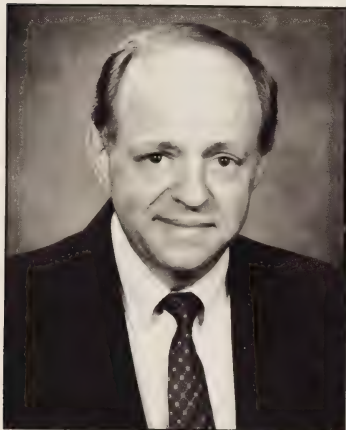
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Patient Counseling

Poison Ivy, Oak and Sumac -- Overcoming the Myths

Thomas A. Gossell, R.Ph., Ph.D., Dean, Ohio Northern University

J. Richard Wuest, R.Ph., Pharm.D., Professor of Pharmacy, University of Cincinnati



This educational program is made possible through a grant-in-aid from

SEARLE

Up to 75 percent of Americans reportedly are sensitive to poison ivy, oak and/or sumac. At the same time, many people cannot recognize these plants. Victims of skin lesions caused by these plants often seek the assistance of a pharmacist before, or in lieu of, a physician. It is the goal of this lesson to assist in providing advice to these individuals.

The Myths

There are strong beliefs about poison ivy, oak and sumac contact. Some are accurate, while others are not.

Myth #1: Everyone Recognizes Poison Ivy, Oak and Sumac. The common three-leaf arrangements of poison ivy and oak plants may be their only consistent characteristic. There are individuals, including those who spend prolonged periods of time outdoors, who still have trouble recognizing the plants. One reason is the plants can assume a wide variety of sizes, shapes and colors, depending on where they are growing. Figures 1 and 2 are line drawings of the three plants which may aid in their recognition. Unfortunately, the plants are hardy and grow in adverse conditions of soil, water, and sun, creating difficult, but not impossible, eradication problems.

Poison ivy, the most common source of exposure, usually grows as a woody vine attached to trees, rocks, fences or other objects. It may grow along the ground as a creeping vine. Free-standing shrubs and bushes exceeding six feet in height have also

been reported.

The pointed and oval-shaped leaves grow on a stalk usually three to four inches long. In spring and summer they are green. During dry spells, late summer and on into autumn, they change coloration to various shades of yellow, red or brown.

When flowers are present, they are arranged in loose, irregular clusters at the axis of the leaves with white-to-green coloration. Grayish-colored, waxy fruits with vertical grooves are sometimes present. These fruits may remain attached throughout the winter.

There are two major varieties of poison oak. Eastern poison oak is an erect, perennial plant that normally grows as a low, woody shrub which does not climb. It is found along sandy areas, or in the dry soils of oak or pine groves. Western poison oak grows as an upright shrub with numerous stems emerging from the ground. It may appear as a vine on a tree, telephone pole or clinging to other vines.

Like the poison ivy plant, poison oak leaves grow in three-leaflet clusters. However, they are irregularly lobed and more closely resemble oak tree leaves. The plants have white-to-green flowers which may or not mature into flattened, berry-like fruits. These may also remain on the plant throughout the winter.

The shape and color of poison oak leaves can vary depending on where the plants grow and the time of year. Leaves are narrow and thin in

extremely shady areas. In full sunlight, they are thick and glossy. Alongside dusty roads, they are normally dull and lusterless.

The goals of this lesson are to identify common myths about poison ivy, oak and sumac, review the sensitization process, and discuss the major symptoms of contact dermatitis caused by these plants.

At the conclusion of this lesson, participants should be able to:

- Identify the active constituent of poison ivy that causes lesion to erupt.
- Select the major symptoms caused by contact with poison ivy, oak or sumac.
- Exhibit an understanding of how to respond to myths associated with sensitization to poison ivy, oak or sumac plants.
- Demonstrate knowledge of the sensitization process caused by contact with poison ivy, oak or sumac plants.
- Choose from a list, information to convey to patients who ask about poison ivy, oak or sumac reactions.

The leaves of poison sumac resemble neither poison ivy nor poison oak. The seven-to-13 leaflet clusters are arranged in pairs, with a single leaflet projecting from the middle. Poison sumac generally grows as a tall woody shrub, or coarse small tree.

One factor that prevents many people from recognizing these plants is that they do not all grow universally throughout the country. Poison ivy is found in nearly every part of the U.S. with the exception of Nevada and California. Eastern poison oak grows within a large triangular area bounded by New Jersey, Texas and

Florida. Western poison oak is found along the west coast from southern Canada to Mexico. Poison sumac is confined mostly to areas east of the Mississippi River. It grows preferentially in swampy, moist, boggy areas.

Therefore, it is possible that an individual who has never traveled outside the West may not have seen either poison ivy or poison sumac. Or, an individual from a metropolitan or large urban area who rarely visits the countryside may not have seen any of these plants at different periods in their development. They cannot associate any particular feature with the potential to cause dermatitis.

Each plant does have one factor in common. They all contain the same active allergen, an oleoresin complex called urushiol. As a group, poison ivy, oak and sumac are the most common causes of plant-induced dermatitis in the United States.

Poison sumac is the least common cause of plant-induced poisoning of the group, owing in large part to the fact that it is generally confined to uninhabited areas. Thus, the remainder of this lesson is concerned mostly with poison ivy and poison oak. The medical problems associated with the two types would be characteristic of poison sumac.

Myth #2: Poison Ivy/Oak is a Problem Only in the Summer. A quick explanation of how these plants cause rash should dispel this myth.

Urushiol is distributed throughout all parts of the plant except the flowers, pollen and epidermis. This occurs through a canal system located within the plant structure. Touching an uninjured plant or merely rubbing against it will not cause a rash. When the plant is injured, urushiol is released. As little as one microgram can initiate a rash affecting all sensitized areas of the body of a susceptible person.

Certainly the danger of urushiol poisoning is greatest in the early spring and summer when the plants' sap flow is highest. Another danger almost as great exists in the early fall when leaves are dry and fragile. Also, even though the plant is inactive during the winter months, it is still alive and urushiol is present. Parts of the plant that have been cut away from the base or dug out of the ground still contain urushiol even though they are dead.

A problem can occur in the winter with people who cut or handle firewood. It doesn't matter how recently the wood was cut before bringing it into the home, or if it had been cut and stacked for awhile. Either way, if poison ivy vines growing on it are injured and touched even months after the plant injury, dermatitis can occur.

Myth #3: There Must be Direct Contact with the Plant Before a Reaction Can be Produced. A patient may believe that he has suffered from poison ivy dermatitis without ever

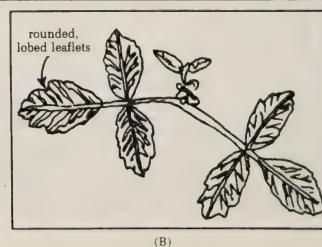
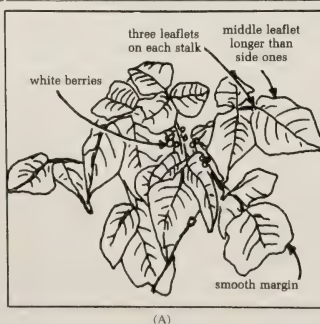


Figure 1
Poison ivy (A) and poison oak (B) leaves.

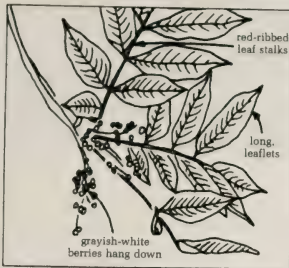


Figure 2
Poison sumac leaves.

coming into contact with an actual plant. What is often unrecognized is that urushiol may be transmitted on clothing or shoes, garden tools, sporting equipment, and animal fur. It may have been picked up on a pair of shoes. When the shoes are worn, the victim is resensitized and the dermatitis reaction occurs. Another scenario is that the family pet may have picked up urushiol while rummaging through the woods. Later, as its owner pets the animal, the allergen is transferred and the dermatitis occurs.

Time will slowly reduce the allergic quality of the causative oleoresin on clothing and other inanimate items. Washing the items in hot, soapy water, or dry cleaning, if appropriate, is the best way to remove the danger of subsequent contamination. Rubber or plastic gloves should be worn while handling and washing the pet.

Myth #4: Dermatitis Rash Can be Prevented by Washing After Exposure. This myth has some truth to it. If urushiol is removed from the area with soap and water within 5 to 10 minutes of exposure, a reaction may be aborted, except in highly sensitive persons. Washing does remove urushiol from the skin before it can be absorbed, but it must be done as soon as possible after contact with the allergen.

A study was undertaken to look specifically at this concept. Persons who were highly sensitive to urushiol, were included. Injured leaves were applied directly to their forearms. Washing within 30 minutes prevented the reaction in some, but not all of the less sensitive individuals.

Washing at 60 minutes was totally ineffective in all persons, regardless of their degree of sensitivity.

Urushiol penetrates the skin rapidly. Once this happens, it attaches to skin protein to form the allergen. This sets off the allergic response. A few minutes after exposure, it cannot be removed, even with the strongest surgical soap.

Myth #5: Some Persons are Naturally Immune to Poison Ivy Dermatitis. Though it is a well known fact that there are people who have never experienced a poison ivy reaction, and these individuals believe they are immune, the concept is a myth. Actually they have never been sensitized in the first place. It is true that an individual's immune system may be more or less reactive compared to another person, and thus respond to antigenic challenge at different rates. Some persons are highly susceptible to antigenic challenge and others are only weakly susceptible.

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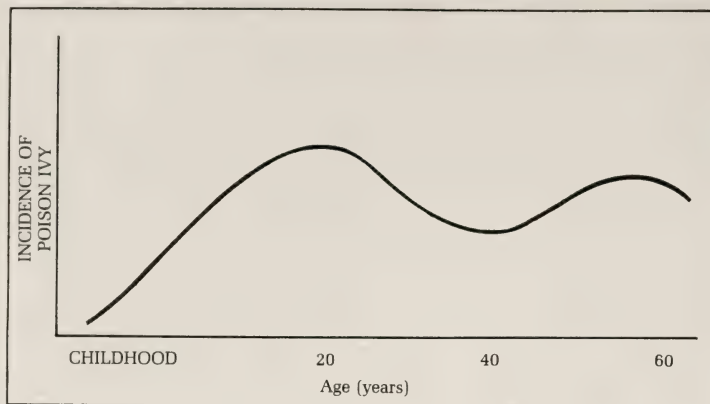


Figure 3
Incidence of poison ivy expressed by the individual's age.

The Allergic Reaction

Urushiol contains a mixture of four chemicals, all of which are sensitizers. Urushiol is called a hapten because, by itself, it is not allergenic. Instead, it must first combine with protein from within the body to form antigens. When it contaminates the skin, urushiol binds to skin proteins to begin antigen production. Specific cells produced in the lymphatic system collect in the area and transport these antigens to the reticuloendothelial system. There, antibodies are formed which are then carried back through the vascular system where they are deposited ("fixed") under the skin.

The first time an individual comes in contact with urushiol, this reaction is initiated. Each subsequent contact adds to the total quantity of antibodies produced. The initial contact may occur even without the person's knowledge. The degree or extent of each dermatologic response is dependent on prior sensitization, which may have occurred weeks or even years before, and on the quantity of antibodies formed.

Once sensitized and sufficient antibodies are present under the skin, the individual may experience poison ivy dermatitis reactions every time he comes into contact with urushiol, for

the rest of his life. As with other immune processes, the extent of reactivity normally recedes with advancing age. Additionally, some individuals who experience an especially severe reaction early in life are less sensitive thereafter. This may be due to a process similar to hyposensitization, which will be discussed in a future article.

Occurrence

As was mentioned earlier, it is estimated that as many as 75 percent of all Americans are sensitive to poison ivy. Occurrence is correlated to age, as depicted in Figure 3. Infants and very young children are rarely affected. Sensitivity must be acquired from exposure. Also, the reticuloendothelial system of small children is not sufficiently functional to produce antibodies. This system develops with age.

After an initial surge during the teens when outdoor activities are highest, the incidence of dermatologic reactions seems to decline between age 20 and 40. Perhaps the increase in incidence of reactions observed during the 40's and 50's is due to spending more time in the yard or with the grandchildren. Then, as we age, the reticuloendothelial system becomes less responsive to

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sensitization. Antibodies which were formed years before are less reactive. With advancing years, many people are exposed to the cause less frequently.

Myth #6: Poison Ivy is Contagious and Spread by Blister Exudate. Of all the misconceptions about poison ivy/oak, this is one of the most common. The myth is perpetrated because a rash frequently appears initially on one area of the body; then, perhaps days later, it may appear on another. Or, streaking of the rash appears after scratching an area. The person interprets this secondary reaction as a response to having spread the disorder through scratching the original rash and contaminating the other sites with blister exudate.

The exudate from blisters of poison ivy/oak lesions does not spread the rash. This fluid is serum that collects in response to an allergen-IgE-mediated inflammatory reaction occurring beneath it. There is no urushiol present in this exudate. In fact, experiments have demonstrated that when the liquid from blisters of one individual is placed on the skin of another sensitized individual, the second person will not develop the rash in response to that application.

The reason a rash appears at a secondary site later is because various areas of the body have differing levels of reaction to the allergen. The same reasoning holds for the "streaking" response. Streaking occurs because this is the pattern in which the specific antibody that is formed in response to antigen stimulation becomes fixed to the skin. However, the concentration varies in different areas of the body.

A sensitized individual who comes into contact with the allergen will most likely experience the first symptom of rash at or near the site of original contact that caused the initial sensitization, regardless of where the urushiol was actually absorbed. With time, as other sites (those having lesser concentration of antibody) become activated by interaction with circulating antigen, they also develop the typical rash. So the appearance of the delayed response is independent of scratching the initial rash, or contamination of one part of the body with blister exudate from another.

Symptoms of Poison Ivy Reactions

Symptoms appear within 12 to 24 hours of the first exposure to urushiol. In some persons, symptoms may require three days to appear. Localized itching due to irritation of nerve endings in the epidermis usually occurs first. Soon after this first sign, patches of redness and inflammation, then warmth, and finally, blisters appear. The blisters can rupture, ooze, and crust after a few days. Tender, thin skin is involved more commonly than hairy areas. Most cases heal without permanent damage.

If itching is not relieved and the victim scratches vigorously enough to break the skin's integrity, infection may follow. On occasion, severely affected individuals

develop complications including blood dyscrasias, kidney damage, occasional psychotic reaction, dyshidrosis (disturbance in sweat production or excretion) and skin pigmentation changes.

Summary

This ends the first of two parts of the review on poison ivy/oak and its treatment. In Part II, the treatment with OTC products, and advice to convey to affected persons will be discussed. **R**

To earn continuing education credit for this article, please complete and return the Continuing Education Quiz on page 11 of this issue. This one-credit hour of Maryland Board of Pharmacy/MPhA approved CE is only \$5 for MPhA members (\$10 for non-members. Allow six to eight weeks for your quiz to be processed and mailed.

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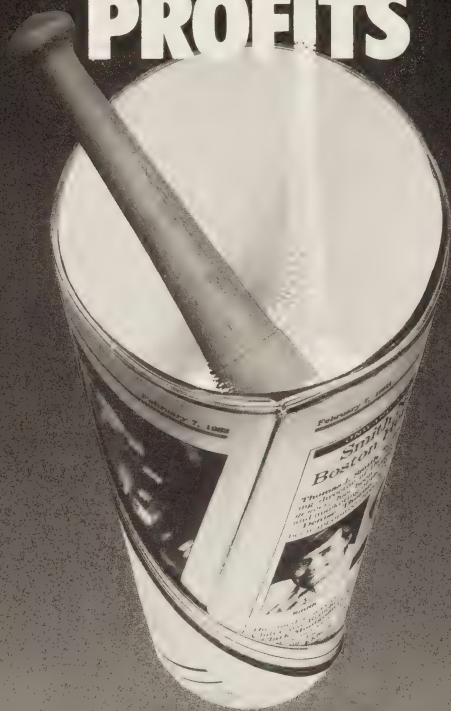
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August 1994 -- Poison Ivy/Part I

This month's questions are taken from the article on poison ivy that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. Members should enclose payment of \$5.00 (non-members \$10.00). The completed quiz for this issue must be received by February 28, 1995. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

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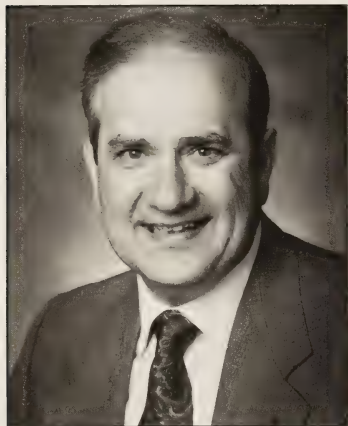
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1. Of the following characteristics, which is the only one that is common to both poison ivy and poison oak?
 - a. both grow solely as climbing vines.
 - b. both change color from green to red in early summer.
 - c. both grow in nearly every part of the country.
 - d. both have a three-leaf arrangement.
2. All of the following statements about urushiol are true *except*:
 - a. it is found in poison ivy but not poison oak.
 - b. it is released when the plant is injured.
 - c. it is an oleoresin.
 - d. it is a sensitizing agent.
3. Urushiol is contained in which of the following parts of the poison ivy plant?
 - a. epidermal layer.
 - b. leaf canals.
 - c. flower
 - d. pollen
4. A chemical such as urushiol that, by itself, is not the allergen is called a (an):
 - a. reacten.
 - b. antigen.
 - c. hapten.
 - d. antibody.
5. In the development of the allergic reaction to poison ivy, which of the following body systems is *least* involved in the process?
 - a. Lymphatic
 - b. Pulmonary
 - c. Reticuloendothelial
 - d. Vascular
6. The type of poisonous plant that has flowers arranged in loose, irregular clusters at the axis of its leaves, and grayish-colored waxy fruit is:
 - a. poison ivy.
 - b. poison oak.
 - c. poison sumac.
7. The type of poisonous plant that contains 7-13 leaflet clusters with a single leaf projecting from the middle is:
 - a. poison ivy.
 - b. poison oak.
 - c. poison sumac.
8. Which of the following is a true statement?
 - a. As little as 1 mcg of urushiol can initiate a dermatitis reaction.
 - b. Once the poison plant has died, it cannot cause dermatitis.
 - c. Poison ivy is only a problem in the summer.
 - d. Touching an uninjured plant will cause a rash.
9. Initial itching of poison ivy dermatitis is caused by:
 - a. reactions with keratin precursor cells.
 - b. migration of lymphocytes to the exposed area
 - c. stimulation of melanocytes in the epidermis.
 - d. irritation of nerve endings in the epidermis.
10. Which of the following is a true statement?
 - a. dermatitis rash can be prevented by washing the exposed area even if it is eight hours later.
 - b. some persons are naturally immune to poison ivy and will not experience a reaction.
 - c. there must be direct contact with the poison ivy plant before a reaction can occur.
 - d. urushiol penetrates the skin rapidly and attaches to the skin protein to form the allergen.

Reports from the 113th Annual Convention

A Year Spent Coping with Change

Howard R. Schiff, P.D., 1993-1994 MPhA President



In life as well as in a profession, there are things that happen over which we have no control, there are things that happen over which we have no control but can influence, and there are things which we can control.

Pharmacy is in the midst of great changes brought on by forces as large and as powerful as any in this country. Health Care Reform as envisioned by President Clinton or most of the other national legislators might well change the way we practice forever. Vertical mergers such as Merck-Paid/Medco, SmithKline Beecham-Diversified, Caremark-Pfizer, and Value Rx-Pfizer, and the rumored Glaxo-McKesson are changing the players and their roles. These are things that happened in the past year and over which the MPhA can do nothing but observe.

In 1993, the Health Care Cost and Access Commission was established by the Maryland Legislature as part of Maryland's Health Care Reform initiative. MPhA was invited to provide the protocols, with the input of the MACDS which were accepted. Our legislative proposals to protect the confidentiality of prescription records and to increase the penalty for forged prescriptions from misdemeanors to felonies were successful. However, efforts to ban discriminatory pricing and "Freedom of Choice" legislation, as part of providers coalition, were narrowly defeated. We should not be discouraged. We are the guys in the "white hats" in Annapolis. We don't speak with "forked tongue". Closer to home, we had aggressive input into

the School of Pharmacy's Non-traditional Pharm.D. Program and the results should be satisfactory to all participants.

The decision of the APhA to endorse Merck-Paid/Medco and its pharmaceutical care program raised a lot of hackles and produced a resolution to disaffiliate at this convention. Serious concerns about the endorsement were communicated to APhA by letter in October and expressed to the APhA at their convention in March.

The above are things we can't control but we can influence. We are players on the state and federal levels.

The final consent order from the FTC was signed this past year. The complaint was five years old; further legal battle would have been too costly and we admitted to no wrong doing. We don't do what they don't want us to do anyway. See "The

*Pharmacy is in the
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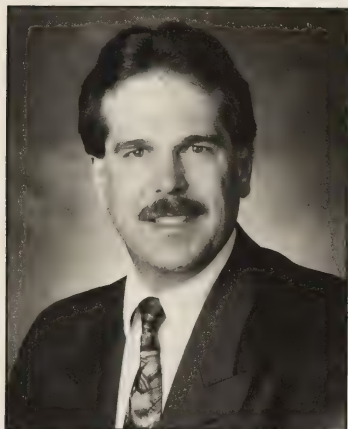
Maryland Pharmacist" April, 1994 issue for further details.

The state legislature opened the Board of Pharmacy to election by all pharmacists in Maryland. As of this writing, those ballots had not been counted. It would not be logical to think that all facets of pharmacy could be represented in such an open

Concluded on page 30....

Reports of the 1993-1994 MPhA Committees

A Recap of a Year of Activity



Legislative Committee
Ernest Testerman, P.D.
Chairman

The Legislative Committee is responsible for reviewing the House of Delegates Resolutions and then to report on how to implement these resolutions to the Board of Trustees. The Committee also has the responsibility to monitor other bills that arise in the Maryland General Assembly during the session that may impact pharmacy.

This year, activity began very early for the Committee. In July we were confronted with Cigna Insurance Company randomly dropping pharmacies from their once open network. We met with the Chairman of the Environmental Matters Committee, Ron Guns, to discuss this problem. It was his Committee who allowed our Patient Access/Freedom of Choice bill to die the year before. We emphasized that our bill would have prevented this type of action by health care plans to drop pharmacies randomly which ultimately inconvenience patients and breaks the patient-provider relationship. However, to our dismay, Chairman Ron Guns said there was nothing he could do to help us. So the fight for Patient Access was again on for the 1994 session agenda.

Also in the Legislative Session of 1993 the Health Care Reform Bill was enacted which provided an avenue for the formation of the Health Care Access and Cost Commission to review most all aspects of health care in Maryland. One of the Commission's tasks was to develop a Standard Benefits Package for small employers to buy for their employees. We were provided the opportunity to develop a pharmacy benefits package for the Standard Benefits Package through the good

work of David Miller and Robin Shaivitz. The Legislative Committee required several meetings to develop a package that was meaningful and affordable but inclusive of pharmacy services that are necessary. This package was introduced to the Health Care Cost and Access Committee for their review and, with only a few modifications, this is now part of the Standard Benefits Package offered to Maryland small employers.

Our commitment of time and resources for the 1994 Legislative Session went toward to five initiatives. These initiatives were: 1) Patient Access; 2) Confidentiality of Prescription Records; 3) Discriminatory Pricing by Manufacturers; 4) Pharmacy Access to Publicly Funded Prescription Benefits Networks; and 5) Physician Assistant Prescribing. Even though we did not win the Patient Access, Discriminatory Pricing by Manufacturers and the Access to Publicly Funded Prescription Benefits Networks, we did achieve several success' this year.

One success was the formation of a provider coalition that includes the physicians, dentists, podiatrists, radiologists, pharmacists and many others. This group worked very hard to develop strategies to pass the Patient Access Bill. As you can see this is a highly charged issue both for us and for the insurance industry. We also had a relationship with the Maryland Association of Chain Drug Stores in the fight to pass the Discriminatory Pricing bill sponsored by Delegate Don Elliott. The formation of these alliances is one of

the Committee's greatest strengths and accomplishments.

The MPhA had success in getting passed the Confidentiality of Prescription Records sponsored by Senator Paula Hollinger and Delegate Virginia Thomas. Also passed this year was a Prescription Forgery Bill sponsored by Delegates Preis and Brewster that the MPhA has been working on for several years. A bill that would cover Off-Label Uses of Drugs passed this year; it will require coverage for payment of drugs used in treatment of diseases not included in the FDA approved list but which is in the medical literature.

The measure of success is not always in the bills an organization can get passed but the ones it can get amended or defeated. Hopefully this in turn will lessen the burden to its members which will ultimately reduce the burden to the end user known as the patient.

My wish for the MPhA Legislative Committee for the future is to build continually upon what has been nurtured so far. We must continue to work with other health care providers through the coalition that formed this past summer. But we must remember that its objective is to enhance the patient's benefit first before our own. We must continue to work with the MACDS for legislation that will create a level playing field in all aspects for retail pharmacy.

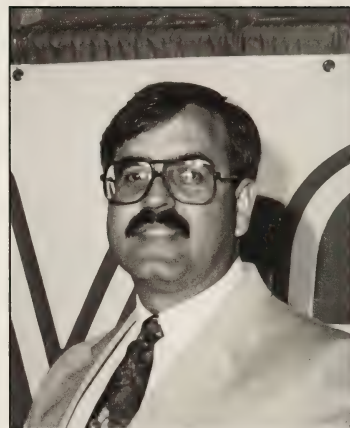
What I see as the most important challenge for MPhA and its committees is to get its members more involved in the legislative process. An organization is only as strong as its members' enthusiasm and support. The leadership can not

do it alone. The leadership can plot the course and monitor the progress but it requires energy to move. This energy for the organization to move comes from involvement from every member and even non-members of the MPhA.

I would like to thank all of those who helped this year in the legislative process. I would like to thank David Miller, Robin Shaivitz, Caren Silverberg, Arnold Davidov, Jim Tristani, Jim Miller, Lance Berkowitz, and Avi Pelta for going to Annapolis to testify on behalf of the MPhA. I would like to thank those who helped me make phone calls such as Leo Mallard, Wally Szot, John Johnson, Ellen Yankellow, Bill Popomaronis and Bob Martin, Jr..

A special "thank you" goes out to everyone on the Legislative Committee for rearranging their schedules to make all those meetings, scheduled sometimes at short notice. For all those pharmacists and family members who wrote and/or called their Senators and Delegates, I thank you, because none of this would have been possible.

The challenge for future Legislative Committee members will be to get personal involvement of more members of the MPhA. So, I challenge all members of the MPhA to become involved and to reach out to non-members to get them to become members and to get involved. The MPhA is a great organization because of its highly talented membership. Thank you. **R**



Third Party Committee

Phillip Marsiglia, P.D.
Chairman

The past twelve months have been very frustrating for the members of the Third Party Committee. The continued movement towards restricted provider networks which often encourage mail order options as well as the downward spiraling of reimbursements have fueled much of this frustration. In addition, the FTC Consent Order recently signed by MPhA, has severely limited the areas in which the Committee can labor. Although the Committee has not discussed subjects which are directly anti-trust in nature, the Consent Order necessitates that we steer clear of any topic which might be misconstrued as a violation of the Order.

On a brighter note, we have worked with the Legislative Committee on the Confidentiality of Records and the Freedom of Choice

Legislation introduced in the past legislative session. The Committee has also continued to foster the cooperative relationship that has been built over the past several years between MPhA and the Maryland Medical Assistance Program. The Committee has worked with the state to update the IDC (Interchangeable Drug Cost) list and the Pharmacy Assistance Formulary of Covered Drugs. Finally, we are currently engaged in discussions with Maryland Medicaid regarding creative reimbursement methodologies which will be advantageous to the state as well as pharmacy providers in the post-OBRA '90 era. R



Budget & Finance Committee
Ronald Sanford, P.D.
Chairman

The primary function of the Budget and Finance Committee is to prepare a balanced operating budget for the Association calendar year. Not unlike other associations, we

come to the budget table with high ambitions to create new and oftentimes necessary programs. Also, not unlike other groups required to present a balance budget, we find ourselves struggling to maintain all the necessary services within the constraints of anticipated income.

Your Budget and Finance Committee composed of Ken Whittemore, Arnold Davidov, Ilene Zuckerman, Nicholas Lykos, Howard Schiff, and Ronald Sanford, worked diligently to propose a budget that, although austere, allowed for the continued growth of MPhA programs. You will note that the budget was accomplished without a dues increase which we felt would be detrimental to membership at a time when we were looking for new members and involvement from members both new and old.

In addition to the presentation of a working balanced budget, the committee wrestled with a number of long range financial issues including:

- the cost of the Maryland Pharmacist journal and additional ways to either generate new income or reduce expenses.
- the continually escalating costs of legislative activity and our paid lobbyist. One alternative recommendation was to offer a CE program on legislative activities and effective lobbying, the proceeds from which could go to a re-activated Lobby Fund.
- when a dues increase would be necessary for a balanced budget in the future.

Other issues were addressed by the committee, I have listed only those on which we spent the greatest amount of debate.

The Treasurer, as chairman of the committee, serves as the "conservative watchdog" over the finances of the Association and guides the Board in working within the guidelines of the approved budget. Not unlike the Congress, in the heat of discussion, we can easily commit the Association to expensive programs not considered in the budget. Unlike the Congress, we have no taxing authority to raise the funds for these programs. It is by constant vigil that we keep our programs and expenditures within the operating budget. I thank the Board for enduring my constant reminder of, "it's not in the budget!".

Finally, my thanks to all the volunteers whose hard work and perseverance keep this association dynamic and healthy, and specifically to the members of my committee, Ken Whittemore, Nick Lykos, Arnold Davidov, Ilene Zuckerman and Howard Schiff who gave freely of their time and advice in accomplishment of our responsibilities. R



An MPhA Convention Scrapbook



It's a "Full House" -- left side -- for the MPhA House of Delegates meeting on Monday, June 20, 1994.



It's a "Full House" -- right side -- for the MPhA House of Delegates meeting on Monday, June 20, 1994.



MPhA members Irwin Rosenberg, Bob Sinker and Rudy Winternitz listen attentively at one of the CE presentations.



Installation of the 1994-1995 Board of Trustees and Officers.



Sabine Casazza, MPhA's new Marion Merrell Dow liaison, chats with President-Elect Jim Tristani in the Trade Exposition.



MPhA Trustees Jean Freels (left) and Ellen Yankellow (right) during the APhA disaffiliation debate.



An MPhA Convention Scrapbook



Jack Peters and Novo Nordisk was just one of 53 exhibitors supporting the MPhA Trade Exposition.



Outgoing President Howard Schiff passes the Captain's Hat to incoming President Arnold Davidov.



Former House Speaker Murhl Flowers can barely contain his excitement as the House debated its resolutions.



Student Sunil Majethia and recent grad Abigail Lagman are just a few of the many young pharmacists who came to the Convention.



Executive Director Dave Miller and staffer Maribeth Porter kept everyone in the spirit for the Polynesian Luau.



Exhibitor Mark Leney and MPhA Past-President Ilene Zuckerman.



An MPhA Convention Scrapbook



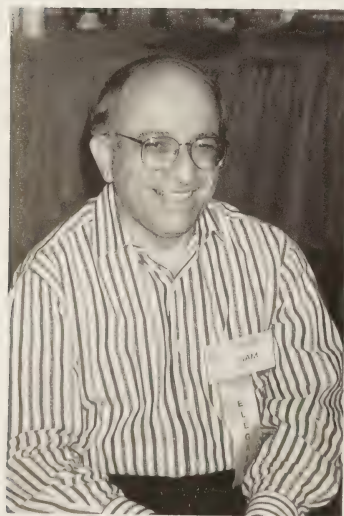
Eugene Street and John Bringenberg during the afternoon CE session.



House Speaker Alisa Billington and President Howard Schiff heave a sigh of relief at the end of the business sessions.



Kathy Gauthier, Maribeth Porter and Ronald Sanford after the Opening Reception.



MPhA Past President Sam Lichter.



Searle sponsored Richard Drinon to speak about complete customer satisfaction.



Outgoing Chairman Nick Lykos installs the newest Trustees and officers.



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Pharmacist Quiz

What resources can help pharmacists promote the value of their patient-care services to the public?

- ☐ a. **National Pharmacy Week** promotional kit
(October 23-29, 1994)
- ☐ b. **"Talk About Prescriptions" Month** planning kit
(the month of October)
- ☐ c. All of the above



Answer a: National Pharmacy Week. October 23-29, 1994. The American Pharmaceutical Association (APhA) is the official source of National Pharmacy Week promotional materials. APhA members can order their free promotional kit by writing Trexco, APhA's promotions company, 1251 Gordon Park Road, Augusta, GA 30901 or by calling 800-950-7701, ext. 55. APhA members must include their membership number and non-members should send a check for \$5, payable to Trexco.

Answer b: "Talk About Prescriptions" Month. the "Talk About Prescriptions" Month planning kit is produced by the National Council on Patient Information and Education (NCPiE). It is available by sending a \$5 check to "Talk About Prescriptions" Month kit, NCPiE, 666 11th St. NW, Suite 810, Washington, DC 20001. For more information about "Talk About Prescriptions" Month, call 202-347-6711.

Answer c: All of the above. If you chose "c," then you're on your way to better visibility in your community! (Both kits will be available around August 1, 1994)

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1. Outpatient prescription medicines account for approximately what percent of total health care spending?
a. 5% b. 10% c. 15% d. 20%
2. How many years of patent life typically remain once a new drug is approved for marketing?
a. 17 b. 10-12 c. 3-5 d. 5-7
3. Which amount is the closest to the actual cost of dispensing a prescription in a full-service pharmacy?
a. \$2.00 b. \$3.35 c. \$6.00 d. \$1.25
4. Out of every ten new drugs marketed, on average, how many achieve sufficient revenue to cover costs and make a profit?
a. 8 b. 2 c. 6 d. 1
5. Considering drug prices and manufacturing wages in the U.S. & Mexico, how long do Mexicans work compared to Americans to pay for Rx drugs?
a. same # hours b. Half as long c. more than twice as long
6. What is the current estimated cost of bringing a new drug to market?
a. \$175 million b. \$359 million c. \$500 million d. \$100 million
7. Which component of health care costs are patients most aware of because they pay out of pocket?
a. physician b. prescription c. hospital d. emergency room
8. What percent of sales, on average, is spent on research by research-intensive pharmaceutical manufacturers?
a. 25 b. 16 c. 8 d. 11
9. Total health care expenditures have risen to almost 13% of GNP since 1960. How have pharmaceutical costs behaved as a % of GNP during that period?
a. risen to 3% b. fallen to 0.5% c. held nearly constant under 1%
10. If pharmaceutical industry profits were eliminated, how much would this reduce total national health care costs?
a. 3% b. 5% c. less than 1% d. 10%

Answers: 1 a. 5%; 2 d. 5-7; 3 c. \$6.00; 4 b. 2; 5 c. more than twice as long; 6 b. \$359 million; 7 b. prescription; 8 b. 16; 9 c. held nearly constant under 1%; 10 c. less than 1%



MPhA's 1994 Award Recipients

Presented at the 112th Annual MPhA Convention



Ronald Sanford (l) receives the Seidman Distinguished Achievement Award from Past President Elwin Alpern (r).



House Speaker Alisa Billington receives a gavel and personalized plaque from President Howard Schiff.



Phil Weiner was awarded the Dupont Innovative Practice Award for implementing personalized patient services by Ilene Zuckerman.





McKesson representatives Vice President of Sales Joe Schwemin and Richard Lambert present Howard Schiff with a special plaque.



Outgoing President Howard Schiff receives the Merck Distinguished Services from representative Frank Radigan.



Incoming President Arnold Davidov receives the NARD Leadership Plaque from Outgoing President Howard Schiff.



MPhA President Howard Schiff, Arnold Davidov, and APhA Executive Vice President John Gans.



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Litigation Update

Expert Testimony Fails to Implicate Homecare Pharmacy

David B. Brushwood, R.Ph., J.D.



Allegations in a recent Missouri case indicate that a woman was hospitalized for treatment of a foot condition, during which she was administered gentamicin. During her hospitalization, her gentamicin levels were monitored.

After eleven days of hospitalization, the patient's gentamicin therapy was continued at home under the supervision of home health care providers, one of which acted as the pharmacy and compounded the medication, the other of which visited the home three days per week and helped with outpatient administration of the medication.

Despite the fact that the patient was receiving gentamicin at the same dosage and frequency as she received at the hospital, her physician did not order outpatient monitoring. After seventeen days of un-monitored home gentamicin therapy, the patient suffered a spell of dizziness and a loss of balance. These problems persisted, and the patient filed a lawsuit alleging negligence for causing her permanent dizziness and disequilibrium. The basic theory of lawsuit was that the patient should have been monitored for toxic side effects of gentamicin following her hospitalization, and that the defendants owed her a duty to monitor.

The physician settled with the patient for \$425,000 and the lawsuit continued against the pharmacy and the home health care agency.

Critical to the patient's case was the testimony of an expert witness, whose deposition had been taken a year prior to trial. At deposition, the expert had testified that he could not state that the gentamicin caused the patient's problems. However, at trial he stated his opinion that the gentamicin did cause the problems.

The trial court refused to permit this testimony because of a rule that requires an expert who changes an opinion before trial to update the information for the opposing party. No such update had occurred, producing an unfair court's ruling, and the case was dismissed due to the lack of expert testimony. **R**

Based on *Green v. Fleishman*, 1994 Westlaw 269575 (Mo. App. June 21, 1994). Copyright 1994, David B. Brushwood. All rights reserved. Reprinted from *Dickinson's Pharmacy*, August 1994.

About the Author

David Brushwood is Professor of Pharmacy Health Care Administration at the University of Florida. His articles on cases affecting pharmacies and pharmacy are provided as a courtesy to state pharmacist associations. Questions on legal issues affecting Maryland practice should be directed to your legal representative or the Maryland State Board of Pharmacy.

Critical Thinking & Communication Skills

Pharmaceutical Care

Jim Bresette, Pharmacy Student, UMAB School of Pharmacy

This article is the sixth in a series written by pharmacy students in the first course of the new entry-level Pharm.D. program at the University of Maryland School of Pharmacy. PHAR 516 (Pharmacy Practice and Education) is an introductory course which exposes the students to pharmacy practice, pharmaceutical sciences, ethics, communication, and critical thinking. One of the class assignments was to write a critical evaluation on one of three topics: pharmaceutical care, pharmacy technicians, or mail-order pharmacy. This course was developed by MPhA Past President Ilene Zuckerman with the assistance of MPhA member and graduate student Diane McNalley.

Is there an ideal environment in which pharmaceutical care can flourish? In *Pharmacy, Drugs and Medical Care*, the authors consider the future of pharmacy past the year 2000. They propose that the most important issues facing pharmacy directly relate "...to the crucial question of how to provide good pharmaceutical care in the complex American medical care system" today and in the future.¹ That these issues "...involve the identification of barriers to the provision of better services..." and determining "...ways to surmount or circumvent them..." is not surprising.¹

Throughout the literature, there exists a common thread that suggests pharmacy and its current method of practice is falling short of its responsibilities and is in the imminent danger of being overwhelmed by technology and market forces. This environment is providing unprecedented opportunity for pharmacy to develop rapidly into a new profession.¹ Indeed, the desire of those in the profession to shape their own futures has resulted in several philosophies aimed at reigning in this juggernaut and providing much needed direction.

The concept of pharmaceutical care, defined by Hepler and Strand in the 1989 keynote address to the "Pharmacy in the 21st Century" strategic planning conference, has not only captured the attention of the profession but seems destined to serve as the primary blueprint for pharmacy's future. Though most state and national pharmacy organizations have embraced the pharmaceutical care philosophy and much has since been written on the topic, there remains a great deal of uncertainty how to put the concept into practice. The uncertainty can best be summarized by a question that asks in what environment can pharmaceutical care be best implemented as the new standard of practice? The response is best framed in terms of the attitudes of those primarily affected - pharmacist and the patient.

How do the attitudes of pharmacists and patients affect the implementation of pharmaceutical care? Quite simply, no environment for pharmaceutical care exists if these key players vigorously oppose the concept. Accordingly, a favorable implementation environment is not a specific locations or setting, but rather a state of mind that must exist in the participants before actual specifics such as reimbursement and logistics and be addressed. To suggest otherwise is placing the cart before the horse.

Clearly then, the necessary implementation infrastructure must be firmly founded in principles that are well understood and benefits that are easily perceived. Assuming that both pharmacists and patients agree that a measure designed to provide better health care is worth pursuing, it seems reasonable

Although much has been written about pharmaceutical care, there remains a great deal of uncertainty how to put the concept into practice

to conclude that both could be persuaded to accept the new measure provided their benefits exceed their losses. From this point, a simple cost-benefit analysis should help define the conditions that would allow pharmaceutical care to be accepted as the new standard of practice.

The premise behind pharmaceutical care calls for pharmacists as a group to assume more responsibility for their patients' therapeutic outcomes and quality of life than is now commonly practiced. Discounting the immediate altruistic and professional reasons, why would pharmacists knowingly advocate a change that is bound to add to their present workload? Reviewing the current literature on the future of pharmacy practice provides two ready reasons for pharmacists to work on their own behalf.

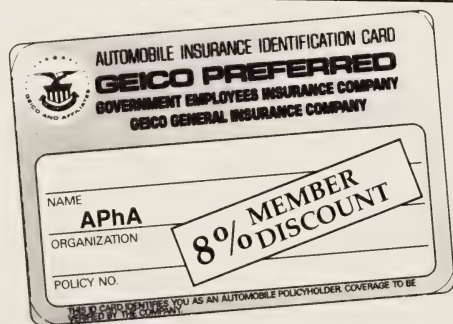
First, the nature of the rapidly changing health care environment demands a response. The Omnibus Budget Reconciliation Act of 1990 essentially forced pharmacists to counsel Medicaid patients and establish drug use reviews in an effort to keep down the program's cost. If this was not regarded as a harbinger, then the Clinton administration's present health care reform initiative emphasizing lower costs and new reimbursement schemes should serve as a wake-up call for even the most intractable.² Additionally, the force of law may now back the concept that pharmacists have an obligation to counsel their patients. In a review of twenty-three legal cases from the 1980's each suit alleged that the defendant pharmacist had a responsibility to do more than correctly

fill a prescription to prevent harm to the patient.³ This litigious trend will undoubtedly continue.

Fortunately, pharmaceutical care addresses several of these concerns. Empirical studies have shown that implementing pharmaceutical care can save money through cost avoidance by reducing morbidity resulting from adverse drug reactions (ADRs) in addition to improving the overall quality of care.^{4,5} Moreover, scrupulous attention to pharmaceutical care documentation designed to track patient progress provides an important paper trail during litigation. In *Beck v. Albany Medical Center*, the pharmacist's written record of dose preparation was deemed admissible evidence to show even though the wrong medication had been given, the patient's injuries could not have resulted from the drug.⁶

A second consideration for the pharmacist involves the current drug-use process in which the physician has the primary responsibility for prescribing. As Hepler and Strand point out, "(d)rug therapy has become so complex that one professional should no longer be expected to control the process alone".⁴ Indeed, if pharmacists do not attempt to fill this gap and move beyond dispensing and physical delivery, they endanger their recognition as professionals and assume the role of well-trained technicians.⁷ Failure to act will result in pharmacists losing control of their profession.

Again, pharmaceutical care as a professional service provides a meaningful response to these issues. By assuming co-responsibility with the physician for therapy



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outcomes, pharmacists would be assuming control of an aspect of patient outcomes that is currently not adequately filled of the fragmented nature of patient care. It seems natural that cooperation among health care professionals rather than subordination of some would add to the effectiveness of the drug-use process. Therefore, the pharmacist's expertise and accountability to the patient imparts professional autonomy upon the profession that is currently lacking. Maintaining a strong self-image as an important contributor to the health care system is essential if pharmacists are to maximize their contributions to their patient's health.¹

The question remains; however, will the patient benefit from the implementation of pharmaceutical care? One need only to the definition to see that it pushes beyond *premium non nocere* (first, do not harm) to actually trying to improve the patient's quality of life. If the profession was presently living up the APhA's 1991 Code of Ethics, it could be argued that the patient's health and safety are a pharmacist's first consideration and as an essential health practitioner, the full measure of professional ability is being provided.⁸ Yet, studies conducted in the United States do not bear this out. In 1971, 140,000 patients died and one million were hospitalized due to ADRs.⁴ More recent studies reported as many as 12,000 deaths and

15,000 hospitalizations due to ADRs.⁴ Research by Knapp and Eisenberg show significantly that appropriate drug therapies reduced the length of hospital stays and costs of care, respectively.⁴ Hepler and Strand summarized these results succinctly. "If the public knew what we know about drug-related morbidity and mortality, it would not just ask that pharmacists institute preventive measures, it would demand such action".⁴

Implementing pharmaceutical care may represent more than merely reform to the patient: it may mean his very survival. From this standpoint, it would appear that adopting any measure requiring increased responsibility from pharmacists would be an improvement. Certainly, Hepler, et. al. consider six major functions basic to pharmaceutical care, the level of which is dependent on patient needs.⁴

1. The pharmacist collects and documents relevant information in a systematic, structured manner for the purpose of determining if the patient is experiencing potential or actual drug-related problems.
2. The pharmacist identifies and lists the drug-related problems the patient is experiencing or at risk of experiencing.

3. The pharmacist establishes and lists the desired therapeutic outcomes for each drug related problems that has been identified.
4. The pharmacist considers and ranks all the therapeutic interventions that might be expected to produce the desired therapeutic outcomes for each problem.
5. The pharmacist decides which therapeutic alternatives to select and records the dosage regimen for each medication for each patient.
6. The pharmacist formulates and documents a pharmacotherapeutic monitoring plan to verify drug-related decisions implemented have resulted in desired outcomes and not in undesirable adverse reactions or toxicities.

Due to the trust they already place in pharmacists, this list of primary functions seems immediately reasonable form the patient's perspective.

What then are the ideal conditions for successfully establishing pharmaceutical care as the standard of practice? Strand notes that since a pharmacist's primary functions remain constant regardless of the setting and other environmental factors whenever pharmaceutical care is practiced, we might safely conclude that for the moment, the key to implementing pharmaceutical care is attitudinal. As such, the major goal of pharmacists and patients is to secure the foundations. **R**

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Annual Report

Concluded from page 12.

election. I'm sure we'll go back to the legislature on this one.

Mothers Against Drunk Driving (MADD) joined with us in a promotion this past winter. Literature and red ribbons were given away in nearly every pharmacy in Maryland. MADD was quite happy with our efforts and we expect to repeat next year.

Our relations with the Medical Assistance Program continued on a high plane. The recent additions to the interchangeable list were provided by the MPhA. The state received one of the best ratings in the country on an adequacy rating by HCFA. With OBRA '90 and its guarantees expiring the end of this year. We're expecting this rating to work in our favor.

So on the things we can influence we did a pretty good job. Community pharmacy, however, remains in peril. We must continue to influence the major forces in this country where we can. After all, someone will have to be in the community to do our job. We are the most qualified, the most dedicated and we are already there.

As this is my last commentary, I'd like to thank everyone. That includes not only the staff, members of the board and committee members but also those that have responded to the commentaries. I'd also have to include thanks to pharmacists among friends, business associates, and old classmates for their input and encouragement and every member for the opportunity and for their confidence. It's been fun! **R**

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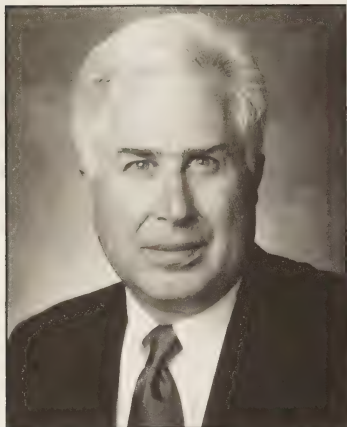
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President's Commentary

Arnold Davidov, P.D., 1994-1995 MPhA President



The big debate at the 112th Annual MPhA Convention was whether or not our organization should disaffiliate from the American Pharmaceutical Association. Many MPhA members were outraged at APhA's endorsement of the Merck/Medco/Paid Coordinated Care Network feeling that our oldest pharmacist organization had sold its and our collective professional soul. Even though the issue was contentious, the House of Delegates conducted itself with the utmost of decorum. The final result, as reported in House Speaker Billington's article on page 5, was that we would not disaffiliate.

Here are some of my personal thoughts on why the I believe we made the right decision.

As president-elect and soon to be president of the MPhA, I thought it just wouldn't be in our best interest to disassociate from APhA. Even though many of you may not know it, the APhA provides substantial support to our organization. APhA disseminates a tremendous amount of useful information covering all facets of pharmacy to the state associations. This information, in the form of position papers, press releases, etc., helps our Board of Trustees to set policy for the organization. It also helps keep our staff current on what's happening in other states.

APhA Executive Vice President John Gans took time out to visit with us at our Annual Convention. He addressed the House of Delegates and explained what APhA was trying to achieve with their endorsement of Merck/Medco/Paid. He spoke candidly about the need for pharmacy to move to reimbursement based on services instead of product. He frankly admitted that their endorsement of this program had caused a firestorm of opposition in many states was less than perfect, and that APhA would be reviewing the arrangement after a year's time. Having made pharmacy care and reimbursement for cognitive services a top priority for MPhA, I felt that we could ill afford additional divisiveness in pharmacy at this critical time.

Frankly, I was also impressed by the fact that John Gans took the time to personally attend our annual meeting. He knew full well the betrayal and frustration felt by some of our members. I believe that his personal involvement, honesty, and candor helped our House of Delegates come to a better understanding of their position.

These are just a few of the reasons why I believe disaffiliation would not have been right for either of our organizations. Maybe next year members will be angered by NARD.... or by ASCP.... or even at the activities or one of our local associations. As I mentioned in my Commentary last month, we can't afford the luxury of fighting amongst ourselves when there are so many working against us. I hope that if and when such discussions about disaffiliation occur again, regardless of who is involved, we recognize that we are better off working together than against one another. R

1994 Resolutions

New MPhA Policies Adopted by the House of Delegates

Alisa Billington, P.D., 1993-94 Speaker, MPhA House of Delegates



Each year, the Association reviews and discusses issues facing the profession at the House of Delegates' meetings during the Annual Convention. The House of Delegates, composed of pharmacists from the ten affiliated local pharmacist associations, recognized organizations (e.g., MSHP, the School of Pharmacy, the Maryland Association of Chain Drug Stores), MPhA trustees, and other members, is responsible for developing policies that guide the Association's Board and staff in responding to and taking action on requests, legislation, regulations, and much more.

Resolutions, the term used for the issue or topic under discussion, are solicited from the membership every year. Some come from individual members concerned with a particular aspect of pharmacy practice. Others come from the affiliated or recognized pharmacist associations. Still others come from the Association's Committees or Board of Trustees. Only members or groups of members may submit a resolution.

Topics taken up in the past range from the highly controversial (the endorsement of the School of Pharmacy's plans for an all-Pharm.D. program) to the mundane.

Once submitted, the House Resolutions Committee is responsible for reviewing and recommending a position on each resolution before it is presented to the full House of Delegates. Chaired by the Vice-Speaker, the House Resolutions Committee serves an important function. It works with submitters to make sure that the language and grammar say what the submitter really wants to say.

The Committee also takes a position on each resolution -- adopt, defeat, refer to a committee for additional study, or to table.

Why have a Committee make a recommendation before the whole House of Delegates has an opportunity to debate the issue? Under parliamentary procedure, there has to be some method for getting the issue up for discussion. The only method available is through a "motion." The Resolutions Committee's recommendation takes the form of a motion to initiate debate. It is then up to the House of Delegates to decide whether to accept that recommendation, change it, amend the resolution, etc.

Having served as both Speaker and Vice-Speaker in the MPhA House of Delegates, I can tell you that while emotions often run high, I have always been impressed with how the delegates work to form the policy that is right for the majority of pharmacists and the Association. That is the purpose of a deliberative body and it is testimony to the commitment of our members that our House works so well.

This year, the House of Delegates debated and voted on four separate resolutions. The House Resolutions Committee and its recommendations were represented by Vice-Speaker Joseph Marrocco. Thanks to Joe's efforts, the deliberative process went extremely smoothly. Joe was elected as Speaker for the 1994/1995 Association year and I am proud and pleased to hand my responsibilities over to him.

Resolution 2

Topic: Regulation of Out-Of-State Pharmacies

Submitter: MPhA Legislative Committee

Whereas the Maryland Pharmacists Association's House of Delegates passed a resolution seeking regulation of out-of-state pharmacies who dispense and/or deliver medications to citizens of Maryland; and,

Whereas the Association requested that this regulation be initiated by the Maryland State Board of Pharmacy as the governmental agency charged with the protection of the public health as that health relates to pharmacy; and,

Whereas the Maryland State Board of Pharmacy has advised the Association that of its preference that the Association initiate legislative actions to accomplish this goal;

Therefore, be it resolved that the Maryland Pharmacists Association shall pursue legislation requiring out-of-state pharmacies which dispense and/or deliver prescription drugs to Maryland citizens to obtain a Mary-

land pharmacy permit and comply with all statutes and regulations pertaining to pharmacy practice in this state.

The House Resolutions Committee recommended adoption of this resolution. After debate, the resolution was adopted as policy on a vote of 43 to 11.

Resolution 3

Topic: Board of Pharmacy Nominating Procedure

Submitter: Resolutions Committee

Whereas in 1992 the Maryland General Assembly altered the nominating procedure to permit any pharmacist to be considered for appointment and to allow all pharmacists to participate in the voting and selection process; and,

Whereas while this alteration was well-intended, it has had an unforeseen and potentially deleterious impact on the effectiveness of the Board of Pharmacy as well as the

careful balance of pharmacy practice representation by Board commissioners; and,

Whereas the effectiveness and fairness of the Board of Pharmacy is essential to the protection of the public health as well as the appropriate regulation and monitoring of professional pharmacy practice in Maryland;

Therefore, be it resolved that the Maryland Pharmacists Association, in cooperation with other state based pharmacist and pharmacy organizations, shall seek a legislative remedy to the changes made by the General Assembly in 1992.

The House Resolutions Committee recommended adoption of this resolution. After debate, the resolution was adopted by the full House.

Concluded on page 8....

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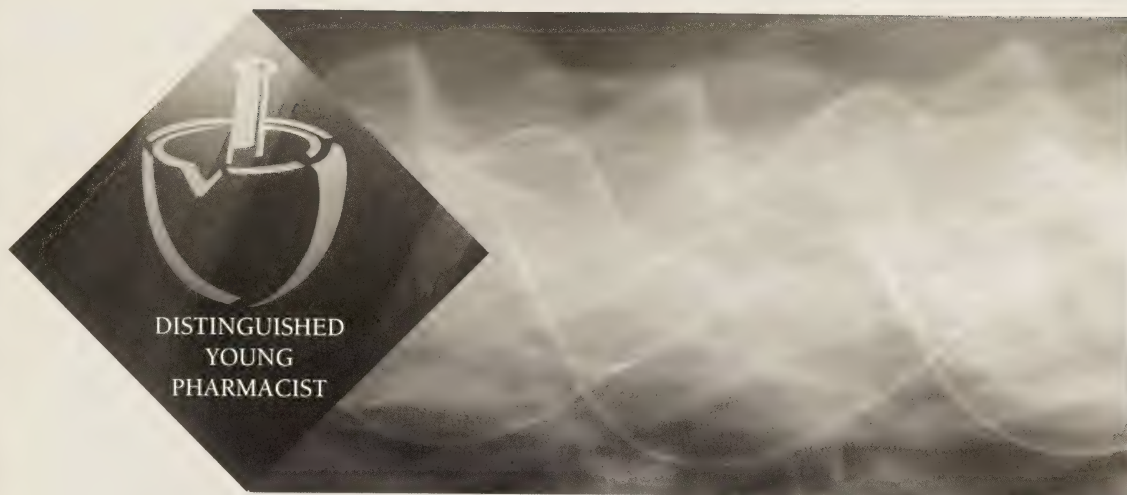
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Resolution 4

Topic: Diagnosis or Indications on Prescriptions

Submitter: S. Ben Friedman, P.D.

Whereas, pharmacists are now mandated by Federal and State law to provide counseling to Medicaid recipients; and,

Whereas, an essential piece of information for patient counseling is a diagnosis, indication, or statement of the patient's medical condition; and,

Whereas, this information is not readily available from the prescriber or from the patient thereby hampering our abilities to provide professional counseling and appropriate pharmaceutical care;

Therefore, be it resolved that the Maryland Pharmacists Association shall pursue legal, regulatory, or voluntary cooperative efforts with Maryland prescribers to have the patient's diagnosis, medical condition or symptoms indicated on each new prescription; and,

Be it further resolved that adequate safeguards to maintain patient confidentiality be incorporated such as the use of recognized diagnosis code numbers.

The Committee recommended that this resolution be referred to an MPhA Committee for further study and review. Speaker Billington conducted debate on the resolution. The House voted against a motion to refer to Committee. A subsequent motion to adopt the resolution as policy was made and seconded. The resolution was adopted.

Resolution 1

Topic: Disaffiliation from American Pharmaceutical Association

Submitter: Ernest Testerman, P.D. and Gerard Herpel, P.D.

Whereas the Maryland Pharmacists Association is an association that represents pharmacists in the State of Maryland; and,

Whereas the Association has taken

positions that promote patients' rights to choose the pharmacist and pharmacy of their choice; and,

Whereas recent decisions by the American Pharmaceutical Association are contrary to the positions of the Maryland Pharmacists Association,

Therefore, be it resolved that the Maryland Pharmacists Association should terminate its affiliation with the American Pharmaceutical Association because of APHA's recent endorsement of a plan belonging to a pharmaceutical benefit manager which promotes other discriminatory plans that directly result in restricted patient access to the pharmacist and pharmacy of the patients' choice; and,

Be it further resolved, that when the Maryland Pharmacists Association is considering or reviewing membership or affiliation in other organizations, it should make one of its criteria that the organization it wishes to join be active in promoting open access for all patients and that the policies of the organizations are complimentary.

Needless to say, this was the most contentious of all the issues debated. A motion to table the entire resolution was offered and defeated. The resolutions original submitters, after conferring, offered an amendment to the motion. The motion carried on voice vote. The resolution was then amended by the House to read as follows:

Therefore, be it resolved that the Maryland Pharmacists Association ~~condemns terminate its affiliation with the American Pharmaceutical Association's because of APHA's~~ recent endorsement of a plan belonging to a pharmaceutical benefit manager which promotes other discriminatory plans that directly result in restricted patient access to the pharmacist and pharmacy of the patients' choice; and,

Be it further resolved, that when the Maryland Pharmacists Association is considering or reviewing membership or affiliation in other organizations, it should make one of its criteria that

the organization it wishes to join be active in promoting open access for all patients and that the policies of the organizations are complimentary.

This final version of the resolution was discussed and adopted by the House of Delegates.

These four resolutions are now formal policies of the Association. Some require action by the Board of Trustees, others will be used in formulating future policy and determining our actions as an organization. **R**



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Last month, the lesson on poison ivy/oak/sumac, common myths were refuted. This month's continuing education article continues with a discussion of treatment of these conditions with OTC products. It concludes with a summary of points that can be conveyed when counseling patients on the treatment of poison ivy/oak/sumac. Because of the similarity of symptoms and treatment of these three conditions, for the purpose of simplicity, the term poison ivy will be used in this lesson to include all three conditions.

There is no known treatment that will eradicate the contact dermatitis caused by poison ivy. Because of its self-resolving nature, treatment is aimed at symptomatic relief.

The choice of treatment of poison ivy depends on the severity of the reaction and the sites on the body affected. Primary objectives are to relieve itching and discomfort. The next objective is to protect damaged skin from further injury and infection until after the acute reaction has subsided. Poison ivy reactions are normally self-limiting, lasting one to three weeks.

A variety of OTC products are available to assist in attaining the above objectives. They are composed of local anesthetics, antipruritics, and skin protectants.

Local Anesthetics

Local anesthetics interfere with the generation and transmission of nerve impulses from an affected area to the brain. There, the impulses are inter-

preted as itching or pain.

Local anesthetics are thought to inhibit the conduction of impulses stemming from sensory nerves by altering neuronal cell membrane permeability to sodium ions. This interrupts the wave of electrical current (i.e., the sodium/potassium exchange) along neurons which signals the brain that there is a problem peripherally. The condition is still there, but the brain does not comprehend that the lesion is causing itching or pain.

Benzocaine, butamben, dibucaine, dyclonine, lidocaine, pramoxine and tetracaine have all been approved for OTC availability in the U.S. They are effective for relieving itching, pain and discomfort caused by contact dermatitis such as poison ivy. However, they do NOT correct the underlying cause, and additional therapy may be needed depending on the circumstances.

While local anesthetics are available in a number of dosage forms, creams, lotions, gels, sprays and aerosols are better than ointments for treating poison ivy. This is because ointments are best suited for dry, scaly skin dermatoses. The other dosage forms are best for weeping, oozing lesions seen with poison ivy.

The person should read and follow directions on the product selected. Most local anesthetics should be applied to the affected area two to four times a day. Lotions and sprays should be shaken well before application.

Antipruritics

In addition to local anesthetics, there are three types of OTC antipruritics that may be useful to alleviate itching of poison ivy: antihistamines, hydrocortisone and possibly counterirritants.

Antihistamines block histamine receptors and prevent its physiologic activity. Histamine is a component of the physicochemical reactions that occur when foreign protein (antigens) enter the body. With poison ivy dermatitis, the antigen is urushiol. Its entry into the body sets off the antigen/antibody reaction that results in rash and other symptoms seen with poison ivy.

While two dosage forms of antihistamines are available OTC (oral and topical), it has not yet been determined whether they act in the same manner. Systemically administered antihistamines have affinity for histamine's physiologic receptor sites and prevent it from attaching. This blocks histamine-induced itching and also prevents

inflammation. While this is effective for treating conditions such as allergic rhinitis, there is some question concerning the efficacy of using systemic antihistamines for poison ivy-induced itching.

Systemic antihistamines are most effective when taken before the antigen/antibody reaction occurs. With poison ivy, by the time the person learns he/she was exposed to urushiol, the rash usually has already appeared. This does not infer that antihistamines are not effective. Rather, it implies that their effectiveness is questionable. Poison ivy is not an approved indication for systemic OTC antihistamines at this time.

For topically applied antihistamines, the story is different. The mechanism of action for topical antihistamines has not yet been fully determined. At least part of their action is due to blocking histamines receptors, presumably at or near the nerve endings.

But, this action cannot account for all of the therapeutic response. As

stated above, antihistamines must bind with histamine receptors prior to histamine release to be maximally effective. However, topical application in amounts that could hardly be considered adequate for effective histamine receptor blockade can provide relief from itching. And, they can do it less time than it would take to reverse the action of histamine at its receptor sites.

Current thinking is that the benefit of topically applied antihistamines is due to an anesthetic like interruption of neuronal impulses rather than the classic histamine receptor blockade. Topical local antihistamines that FDA considers to be safe and effective for treating poison ivy dermatitis are diphenhydramine and tripeleminamine.

Hydrocortisone was originally available on prescription-only status. Topical hydrocortisone in strengths up to 0.5 percent was switched to OTC status in the early-1980's. More recently, the 1 percent strength was also approved for OTC availability. Through the years, hundreds of millions of people have applied

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hydrocortisone topically to self-treat itching and other skin conditions.

Numerous studies, and its tremendous commercial success, have demonstrated hydrocortisone's effectiveness as an antipruritic. However, for the itching associated with poison ivy, the effect of hydrocortisone may not be felt for a few days and a local anesthetic may provide prompt relief.

Topically applied hydrocortisone has two fundamental actions. It constricts cutaneous blood vessels which hinder mobilization of white blood cells and monocytes into the area where the antigen/antibody reactions are occurring. It also antagonizes the inflammatory response of mast cells and other types of cells that release the mediators of inflammation. These, in turn, reduce impulses to the brain. This relieves the itching. Table 1 lists information useful in counseling patients on the application of topical hydrocortisone products.

Counterirritants include camphor, menthol, and phenol. It is alleged that these agents produce a mild anesthetic effect by means of their counterirritant (i.e., cooling) activity. This means that stimulating cold receptors in the skin (which are more sophisticated than pain receptors) overrides the skin's response to conditions that cause itching.

Itching is considered to be a form of low-level pain. It can be more bothersome than pain, but it is transported via the same pathway. By applying cold or causing a cold sensation as counterirritants do, the brain detects these higher level impulses and itching is alleviated.

Even though they have a long history of use, there is some, but insufficient, evidence of counterirritants being as effective as antihistamines and hydrocortisone for treating itching of poison ivy. They can be marketed for relief of itching, but absolute proof of efficacy is still pending.

The opponents of their use claim that the only beneficial effect of counterirritants is that they "smell like medicine." Until the FDA publishes

Patient Counseling or OTC Topical Hydrocortisone

To properly use this product:

- Wash your hands before and after use.
- Cleanse the skin area with soap and water and pat dry each time you are ready to apply this medicine, unless you were directed otherwise by your doctor.
- Only the medicine that is actually touching the skin will work. A thick layer is not more effective than a thin layer.
- Creams, ointments and lotions: Apply a small amount of the medicine to the affected area and spread it lightly.
- With lotions and aerosol, shake the container well before applying the medicine.
- For aerosols, hold the container straight up, about 6 to 8 inches from the affected skin area and spray for 2 to 3 seconds.

General Information for Patients

- This product is for external use on the skin only. Do not apply it into or near your eyes or mouth.
- Do not apply other creams, lotions or cosmetics on top of or underneath this medicine.
- Do not bandage the area unless directed by your doctor.
- If your condition persists or worsens, or if you have a constant irritation, such as burning or itching that was not present before you started this medicine, call your doctor.
- Do not use more often or longer than recommended on the label.
- Read all labels before using this product. If you have any questions, ask your doctor or pharmacist.
- Keep all medicines out of the reach of children and do not keep or use outdated medicines.

Adapted from the Pharmex PALs (Patient Advisory Leaflets). For more information, call (800) 233-0595.

Table 1

its final ruling, one should not ignore the psychologic benefits this has for some people.

Skin Protectants

It is well known that substances which provide a mechanical barrier to protect skin surfaces from harmful and annoying stimuli will prevent urushiol from penetrating and causing dermatitis. However, these skin protectants (e.g., allantoin, aluminum hydroxide gel, calamine/zinc oxide) have not, at this time, been proven to actually alleviate itching, dry oozing exudate or affect the overall course of case of poison ivy dermatitis.

Two skin protectants that have met the test and are on the list of

safe and effective poison ivy remedy ingredients are colloidal oatmeal and sodium bicarbonate (baking soda). According to the FDA, these agents may claim to "provide temporary skin protection and relieve minor irritation and itching due to poison ivy, poison oak, poison sumac {and insect bite}." The agency will not, however, allow the claim, "Dries the oozing and weeping of poison ivy, etc."

Products containing these agents must carry the warning, "If the condition worsens or does not respond within 7 days, consult a doctor." This is good advice for any poison ivy remedy. Not only may the product be ineffective, but a more serious underlying condition may be present. Or, the person may be experiencing an

allergic reaction from an active or inactive ingredient in the product. FDA further advises that these products should instruct the user to apply the product liberally as often as necessary.

The recommended method of using colloidal oatmeal as a soak in a tub is to turn the warm water faucet on to full force and slowly sprinkle one cupful (or package of colloidal oatmeal directly under the faucet as the water runs into the tub. Before entering the tub, the person should stir any colloidal oatmeal that may have settled on the bottom of the tub. Care should be taken when getting into or out of the tub to avoid slipping and falling.

The person should soak the affected area for 15 to 20 minutes as needed. After soaking, the area should be patted dry rather than rubbed so that a thin layer of the colloidal oatmeal will be left on the skin. The process should be done once or twice a day, or as directed by his/her doctor.

With sodium bicarbonate, from one percent to 100 percent can be used as a paste, soak or wet dressing. When used as a paste, sufficient water should be added to the baking soda to wet it. This should be applied to the affected area as needed.

For use as a soak in a tub, one or two cupfuls should be added to a tub of warm water and the area can be soaked for 10 to 30 minutes as needed. As with colloidal oatmeal, the area should be patted dry, not rubbed so that a thin layer of sodium bicarbonate remains.

Baking soda can also be used as a wet dressing by making a solution in a container large enough to saturate a piece of cloth. Any type of clean cloth such as a towel, diaper or torn bed sheet can be used. It should be placed in the solution of baking soda, gently squeezed and applied loosely to the affected area. The cloth can again be saturated in the solution every 15 to 30 minutes and reapplied to the area.

Should Poison Ivy Blisters be Broken?

If dermatitis is sufficiently severe to cause vesicles (blisters), they may be opened carefully. This will allow for easier penetration and absorption of topical medication into the dermis where it is needed. Although commonly misunderstood, blister exudate will not cause a further reaction or spreading of the condition if it touches another part of the body or another person. However, done properly, many experts believe it can be undertaken safely. If the blisters are to be opened, it is best to do it aseptically. Persons should be directed to lance the blisters carefully where they rise

from the skin (not on top) to allow the serum to drain.

Slight pressure can be applied to express the liquid if necessary. The skin on the top of the blister should be preserved because it helps protect the epidermis beneath it from injury and infection, and assist the healing process. Once drained, the area should be blotted and an emollient product applied to keep the area soft and moist.

Many persons believe that blister exudate will cause spreading of poison ivy. The fact is that it does not. Blister exudate of poison ivy tests negatively for urushiol, so it cannot possibly cause sensitization.

Patient Advice for Using OTC Products to Relieve Itching

- This product is for the temporary relief of itching associated with minor skin irritation.
- This product is for external use only. Do not use it near your eyes.
- If you accidentally swallow some of a liquid product, contact a doctor or poison control center immediately.
- Do not use this product on children less than 2 years of age except on the advice and under the supervision of a doctor.
- If you are going to use an aerosol or pump spray product on your face, apply it on your hand or on a piece of gauze or cotton before applying to your face to avoid spraying the product in your eyes.
- If this product contains alcohol, do not use it near a fire or open flame, or while smoking.
- Before you use a local anesthetic, check with your doctor or pharmacist if you have ever had any unusual or allergic reaction to this medicine or other areas of the body.
- Do not apply this product more than 3 or 4 times a day, over extensive areas, or on raw, blistered or damaged skin unless otherwise directed by your doctor.
- If itching is not relieved by use of this product, or it persists for longer than 7 days, see a doctor for further advice. The itching could be a symptom of a serious medical condition.
- If itching worsens, or your skin becomes red, irritated, or inflamed when using this product, stop using it and see your doctor or pharmacist.
- Keep this and all other medicines out of the reach of children.
- Keep your fingernails trimmed short and edges filed smooth to prevent damage from scratching. However you should try to avoid excessive scratching.
- As with all other medicines, follow the instructions listed on the label of this product.

Table 2

Hyposensitization

Dermatologists may use the hyposensitization procedure in patients with recurrent, severe poison ivy dermatitis. It reduces the severity and duration of the allergic response. However, complete sensitization is not accomplished, an often sensitivity to poison ivy returns to pretreatment levels within six months.

Administering urushiol to an extremely sensitive person carries risks. The procedure involves administering a series of doses of urushiol, orally or intradermally, beginning with diluted solutions which are increased in concentration over time. The principle is based on the antigen's ability to stimulate formation of high blood titres of a specific immunoglobulin (antibody) which then combines with urushiol from plants if contact is made later.

If urushiol binds to this circulating antibody, the complex keeps the antigen away from the fixed antibody which would normally alleviate the inflammatory response.

Conclusion

Approximately one-half of all persons with poison ivy, oak or sumac lesions can probably be treated successfully with OTC medications and home remedies. Occasionally, an individual may experience an intensely severe reaction. When this occurs, the patient should be referred to a physician. As with most severe inflammatory responses, systemic steroids may be the treatment of choice for alleviating the person's discomfort. Table 2 lists patient advice for OTC products to relieve itching of poison ivy dermatitis.

R

To earn continuing education credit for this article, please complete and return the Continuing Education Quiz on page 30 of this issue. This one-credit hour of Maryland Board of Pharmacy/MPhA approved CE is only \$5 for MPhA members (\$10 for non-members. Allow six to eight weeks for your quiz to be processed and mailed.

Goals

The goals of this lesson are to discuss treatment of poison ivy lesions with OTC products, and provide information to convey when counseling patients.

Objectives

At the conclusion of this lesson, participants should be able to:

1. Select appropriate treatment for controlling symptoms of poison ivy;
2. Recognize the mechanism of action for drugs used to treat poison ivy lesions;
3. Identify the limitations for various drugs when used to treat poison ivy;
4. Demonstrate an understanding of hyposensitization as a process to reduce the severity of poison ivy bouts; and,
5. Choose appropriate advice to use when counseling patients on the treatment of poison ivy.



Your Pharmacy Practice Involves More Than Drug Dispensing...

When you or your patients notice a drug product problem or you become aware of an unsafe or improper medication use and report it, you play a critical role in drug therapy monitoring, drug product selection, and safe medication use.

The **Maryland Pharmacists Association** encourages your participation in the USP Practitioners' Reporting NetworkSM (USP PRNSM), a nationwide reporting system that enables health practitioners to report all concerns and suggestions involving drugs, radiopharmaceuticals, medical devices, animal drugs, actual and potential medication errors, and adverse events.

USP's staff of health professionals monitors all information received through its programs and provides feedback to those health care practitioners who have taken the time to report. Likewise, USP keeps the industry apprised of product problems received and shares this vital information with the compendia by generating changes in compendial standards and requirements in the *USP-NF* or modifications to the *USP DI*. As a partner in the FDA MedWatch medical products reporting program, the USP PRN shares all information with the FDA and supports their efforts to protect the public health by identifying serious adverse events. Numerous reports received through the Network result in product corrections and recalls.

Take a few minutes to let the USP PRN and your association work with you to make a better health care system for you and your patients.

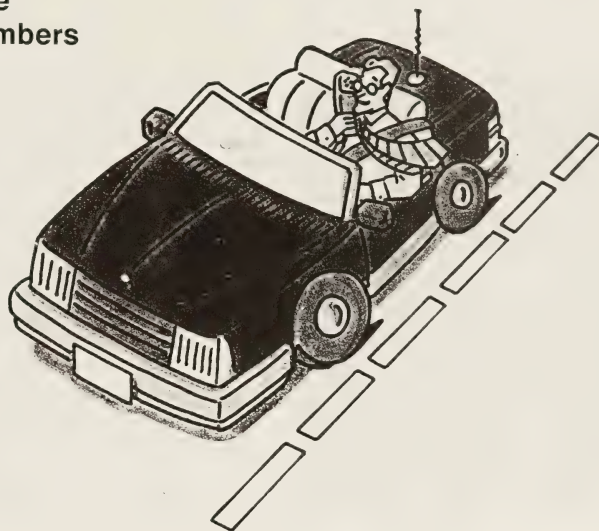
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Litigation Update

A Rude Pharmacist

David B. Brushwood, R.Ph., J.D.



The *Vancouver Sun* has recently reported that the British Columbia Court of Appeal upheld a lower court ruling that the British Columbia College of Pharmacists exceeded its jurisdiction in disciplining a pharmacist for his bad manners. The court ruled that rude treatment of customers does not amount to professional misconduct.

The pharmacist in question, who no longer is licensed as a pharmacist for reasons that were not explained in the article, was disciplined in 1989 for acting in "an extremely rude, condescending and wholly unreasonable manner" toward six of his customers at a Vancouver pharmacy. The College of Pharmacists, which serves many of the functions performed by state boards of pharmacy in the United States, said the pharmacist was "hostile, belligerent, sarcastic, unreasonable and grossly unprofessional." The College imposed restrictions on the pharmacist's business, and it ordered him to pay \$2,000 in hearing costs.

The appellate court ruled that the pharmacist had exhibited bad manners in the context of a business activity, rather than a professional activity, and the manners one uses in business are not the subject of regulation by the College. The court noted that "civility is not amenable to regulation and is not the subject of a generally accepted standard." The court observed that drug control and public safety are the main objectives of the Pharmacists Act, which governs the professional conduct of pharmacists. The court stated: "Regulating and personal idiosyncrasies of its members, including short temper, intemperate language, and rude behavior is not, however, reasonably connected to any objective embodied in the legislation."

The College had determined that the pharmacist's customers were outraged and embarrassed by the pharmacist's attitude and behavior. The extreme nature of the testimony received, and the obviously traumatic effect the conduct had on the testifying members of the public, led the College to conclude that misconduct had occurred. However, this ruling was overturned on appeal. **R**

Based on: "College of Pharmacists Exceeded its Jurisdiction," *The Vancouver Sun*, August 15, 1994, P. B2. Copyright 1994, David B. Brushwood. All Rights Reserved. Reprinted From *Dickinson's Pharmacy*, September, 1994.

About the Author

David Brushwood is Professor of Pharmacy Health Care Administration at the University of Florida. His articles on cases affecting pharmacies and pharmacy are provided as a courtesy to state pharmacist associations. Questions on legal issues affecting Maryland practice should be directed to your legal representative or the Maryland State Board of Pharmacy.

Fitting the Pieces of the Puzzle

Finding the Right Match in Hiring New Employee Pharmacists

Therese Kirklys, R.Ph., President, Pharmstaff, Ltd.



The cost of hiring and then dismissing a new employee pharmacist because of some unforeseen problem can reach into the tens of thousands of dollars. With monetary pressures in pharmacy increasing, finding the right match when hiring new pharmacists has magnified importance.

Finding the right employer and employee match is one of the more difficult tasks a pharmacy manager or owner will have to perform. Unlike dispensing a prescription, monitoring drug therapy, or interpreting test results, choosing the right pharmacist is not a science. There are, however, some things an employer can do to reduce the chances of choosing the wrong candidate when filling an open position.

Sorting the Pieces

Before placing a "help wanted" advertisement, have a concise job description that includes a clear concept of your expectations and a list of duties and responsibilities that are to be assumed by the new employee. This job description will help you focus on the important traits for which you are looking and gives you a set a criteria amongst which to compare all candidates.

A prospective employee's resume will be the basis for a background search, but should be looked at only as a guide. The first task is to identify any obvious factual errors in the resume. For instance, the date of licensure for a candidate could not possibly come in 1986 when he or she claims that the first pharmacy degree was received in 1987. Additionally, it

is commonly known that the University of Chicago is not in New York City. If these kinds of mistakes appear, there is a good chance that this candidate is not being completely truthful.

Carefully look for inconsistencies or breaks in time between periods of employment. Problematic areas can be questioned in a later interview. It is possible that a break of a few months may be for valid reasons, but it may also point to much deeper problems, including lack of licensing, criminal activity or substance abuse.

Along the same lines, look to see if your prospect jumps from job to job. If he or she does, be careful. There may be legitimate reasons for this kind of work history, however, a new employer may be no more than a short-term stop on this candidate's career merry-go-round.

This is the first in a new series of articles dealing with employer-employee relations for members

With regard to education and licensing, checking is relatively easy. Candidates either do or do not have the education and licensing they claim to have. Both licensure status and education can easily be checked through state licensing agencies, and colleges of pharmacy.

Employers should also look for substance in resumes. It is very common for "resume bloat" to occur as potential employees strain to impress employers. Recent college

graduates should not have five page resumes, though this may be appropriate in more accomplished and more experienced prospects. Closely reading between the lines will allow employers to separate substance from filler.

After noting obvious flaws, a more thorough check of the factual information is to be done. Calling and checking work references is just the first step. Information received from past employers may be no more than a confirmation that the person worked there between two dates because employers, fearing law suits, limit their comments.

This is where a pharmacist's network of professional contacts becomes invaluable. Many pharmacists are involved in national, state, or local pharmacy organizations as well as civic groups. When faced with road blocks in checking a resume, employers could turn to those resources to get information about the quality of a candidate's particular work experience that may not be directly available from the previous or current employer.

No matter who you talk to, the last question to ask is whether that person would consider hiring or rehiring this candidate. This answer will give you an indication of the candidate's previous performance.

Other readily accessible information is a candidate's driving record, credit status, and any criminal record or court ordered mental health treatment; all of which give insight into the person whom you are contemplating hiring.

Piecing it Together

Besides the objective criteria, a successful employer/employee relationship is based on an amalgam of such hard to define factors as personality, professional philosophy, and attitude. A pharmacist that may fit perfectly in one setting, may be a complete failure in another. This is generally neither the fault of the employer, nor of the employee, but it does illustrate the importance employers should place on factors beyond the resume.

These are all factors to examine during the interview. It is possible to conduct interviews via telephone, but it is highly preferential to conduct interviews in person because so much more information can be gathered from non-verbal communication.

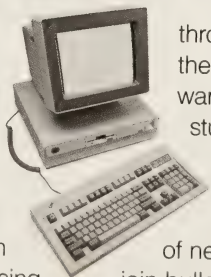
What are new employees looking for? Positions where they can apply their expertise, will continue to learn, and where their efforts will be appreciated!

Whether conducting a phone or personal interview, listen for the quality of the voice. Is there enthusiasm and professionalism? Is the person confident of his or her answers? Ask yourself if this is the person you want interacting with your patients. With an increased emphasis on counseling skills, does this person have the communication skills in order to carry out these responsibilities successfully?

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*Our toll-free, 24-hour job line enables pharmacists
across the country to search for jobs for FREE.
Positions are listed by state and practice setting
enabling recruiters to tailor contracts to meet their needs.*

Fitting in the Last Piece

When a decision has been made to offer a position to a chosen candidate, a number of factors will go into whether the offer will be accepted. Contrary to popular opinion, the level of salary is not the most important consideration in whether a candidate will accept a job. Although, to attract a number of qualified candidates from which to choose, a competitive salary should be offered.

In study after study, the most significant factors in whether or not a candidate accepts a position were: where candidates believe they can best apply their expertise; where they will continue to learn; and where their efforts will be most appreciated. More often, a pharmacist will look at the appeal of the facility and the benefits offered as the top factors in making a decision. For instance, if pharmacists have a particular interest in compounding, hypertension or diabetes, they are more likely to

choose a facility that would allow them to use their specialized interests and knowledge.

By finding a compatible match, both employer and employee enter into a fulfilling professional relationship that can last for many years. ■

About the Author

Therese Kirklys is the founder and president of Pharmstaff, Ltd., a national pharmacy temporary staffing service with corporate offices in Chicago, Illinois. Since founding the service in 1982, Ms. Kirklys has gained experience recruiting and placing pharmacists in a variety of practice settings from Pharmstaff's database of over 20,000 registered pharmacists.

During the interview encourage candidates to share their professional expectations: Where they see themselves in one year? In five years? Even the greatest candidates will not be a good match if their expectations for the future do not fit with those of the employer.

In personal interviews, note the candidate's body language. Are candidates casual or formal in their dress and speech? Will this attitude match with those of the other employees with whom they will work? Do they match yours?

Consider doing drug screening for potential new employees. Given the professional responsibility and subsequent liability, contracting out with a local medical laboratory is a bargain. Today, in our professional world, this is an accepted practice.

Pharmacist Quiz

What resources can help pharmacists promote the value of their patient-care services to the public?

- ☒ a. **National Pharmacy Week** promotional kit
(October 23-29, 1994)
- ☒ b. **"Talk About Prescriptions" Month** planning kit
(the month of October)
- ☐ c. All of the above



Answer a: National Pharmacy Week. October 23-29, 1994. The American Pharmaceutical Association (APhA) is the official source of National Pharmacy Week promotional materials. APhA members can order their free promotional kit by writing Trexco, APhA's promotions company, 1251 Gordon Park Road, Augusta, GA 30901 or by calling 800-950-7701, ext. 55. APhA members must include their membership number and non-members should send a check for \$5, payable to Trexco.

Answer b: "Talk About Prescriptions" Month. The "Talk About Prescriptions" Month planning kit is produced by the National Council on Patient Information and Education (NCPiE). It is available by sending a \$5 check to "Talk About Prescriptions" Month kit, NCPiE, 666 11th St., NW, Suite 810, Washington, DC 20001. For more information about "Talk About Prescriptions" Month, call 202-347-6711.

Answer c: All of the above. If you chose "c" then you're on your way to better visibility in your community! (Both kits will be available around August 1, 1994)

You have the answers...so order your promotional materials today!

Planning for National Pharmacy Week

Promotion Made Easy



October is a busy month for pharmacy! In addition to the month-long celebration of "Talk About Prescriptions Month," the third-week is set aside to honor and promote the profession through "National Pharmacy Week." This year, National Pharmacy Week will be celebrated October 23 through 29.

As part of our service to you, the MPhA member, we are providing you with some ideas, suggestions and resources to help in promoting yourself and your practice during October. These promotional plans are suggestions to help you create community awareness of the pharmaceutical care provided by pharmacists. The public can be informed by personal contact in community pharmacies, hospitals, nursing homes, businesses, and schools and by using the media to tell your story throughout the community.

Take Advantage of Promotional Products

To promote National Pharmacy Week, you don't have to hire your own public relations company. There are plenty of resources already developed to help you at no or nominal cost!

The American Pharmaceutical Association has created a Promotional Kit that contains camera-ready materials for you to copy and distribute to your patients. In addition, they offer a variety of additional inexpensive items. Products include a banner, poster, and balloons can help spotlight the "Communication is Good Medicine" message in your pharmacy, waiting or counseling area,

or at a special event. Other products can be specialized for your practice and provided as giveaways; these include medicine spoons, magnets, and medicine organizers. Four patient brochures are also available to use as "bag stuffers" or as handouts at health fairs and other events. The medication handouts provided in the kit cover such topics as asthma, birth control and STDs, breast cancer, immunization, insomnia, osteoarthritis, osteoporosis, and ulcers.

Employers can recognize staff pharmacists with special gifts like t-shirts, mugs, and squeeze bottles or with some of the year-round items such as "Communication is Good Medicine" buttons and bumper sticks and license plate frames.

To order the APhA Promotional Kit call (800) 950-7701, extension 55, Monday through Friday from 8:00 am to 5:00 pm EST. The cost of the kit is \$5.00 and can be charged to your MasterCard or VISA.

To celebrate the entire month of October as its annual "Talk About Prescriptions Month", the National Council on Patient Information and Education (NCPIE) has put together a media and promotional planner, which includes a free poster. To obtain the planner, call NCPIE at (202) 347-6711.

What Do I Do Next?

You've ordered the kits from APhA and NCPIE, checked out the materials in this issue of *The Maryland Pharmacist* and decided a poster and a bag-stuffer just aren't enough. What can you do to make your pro-

motion of National Pharmacy Week stand out in the minds of your customers, neighbors, and patients? Here are a few ideas that other pharmacists have used and used successfully.

■ **Select a spokesperson(s)** from your pharmacy to visit classrooms and community groups. High school students would benefit from hearing about pharmacy as a possible career. Children can be taught about poison prevention and the importance of taking medications correctly with educational materials available from the Maryland Poison Center. Parents could also benefit from a course on how to educate their children about medication use and what to do in case of poisoning. The spokesperson also could highlight the pharmacist's expertise in helping the parent choose OTC products for their families. Elderly groups, such as retirement communities or civic groups, also would be a good target.

Even pharmacists who aren't in traditional community practice can still be effective in promoting National Pharmacy Week. Consider Robert Hilton at the Medical Center for Federal Prisoners in Springfield, Missouri. He publicized National Pharmacy Week with poster displays, patient information, and a showing of the APhA video "Your Medicine, Your Pharmacist and You" to prison inmates.

■ **Sponsor a "brown bag" review.** This program invites patients to bring all their medications in a bag on a specific day to discuss them with a pharmacist. NCPIC

has a complete "brown bag" kit that includes posters, bags, flyers, etc.

This event has been very successful for many pharmacists. For example, Jack Pross, president of the Onondaga County Pharmacists Association and owner of Lyncourt Drugs in Syracuse, New York was able to convince a local TV station to help sponsor pharmacy week activities last year. The station ran free announcements that pharmacists would be available to review medications during "brown bag" day, and pharmacies throughout the county posted signs. The pharmacists set up booths in five shopping centers and at the TV station. People who brought their medications received information about side effects and drug interactions.

Also last year, members of MPhA's Public Relations Committee and staff sponsored "brown-bag" reviews for the employees of the Social Security Administration, Bell Atlantic, Westinghouse, BGE and the Maryland Department of Personnel. These activities were an outgrowth of the Association's work with the Maryland Department of Aging.

■ **Promote overall wellness by setting up a display** in the pharmacy, a shopping mall, senior center, or even at the local library. The display should emphasize the health benefits of eating right and exercise. Have a kick-off party at the beginning of the week and serve healthy foods and beverages. Explain how certain foods and activities can influence a medicine's effects. Another idea for an educational display is to exhibit medicines and

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You can help the public understand the risk they may face in a medical emergency with a new professionally prepared speaker program for pharmacists.

You can bring this potentially life-saving program to your community to teach the dangers of hidden medical conditions, drug reactions, and drug therapy in emergencies.

This program is endorsed by most state pharmacy associations and by all national pharmacy groups.

To obtain this kit - FREE OF CHARGE - Write: Director of Professional Programs, Medic Alert Foundation, Turlock CA 95380

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In Medical Emergencies

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Pharmacist Speaker Kit

Pharmacist's Speakers Guide

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other health-related products to keep in the home to treat minor ailments and accidents.

■ **Set up a booth in a shopping mall** or a special area in your pharmacy. Distribute important health information like the brochures and patient handouts available to pharmacists.

■ **Organize or participate in a health fair** to demonstrate how pharmacists interact with other health professionals to ensure the quality of patients. Focus on educating parents about their children's health. Child immunization and poison prevention are two areas in which parents need more information.

Last year, the pharmacy department at Olympia Fields Hospital and Medical Center in Olympia Fields, Illinois sponsored a Children's Health and Safety Fair. The fair provided valuable information for the public, increased awareness of the pharmacist's expertise, and increased pride among the pharmacists in the hospital.

Don't forget that MPhA has a special table-top exhibit available for you to use. The display comes complete with lights, signs and literature dispensers -- everything you need to advertise your profession or practice. And the best part? It's absolutely **free** to members. For more information, or to set up a date to borrow the display, just call us at (800) 833-7587.

■ **Compile a list of patient support groups** and distribute it to your patients during the month of October as a counter brochure or similar stuffer. See the table on page 29 that lists national resources for a good start. Add in local groups from your community.

Focus on different diseases or conditions (arthritis, asthma, birth control, high blood pressure, osteoporosis, STD prevention, sleep disorders, ulcers) throughout the week and provide information on warning signs, detection, treatment, and support groups. Contact the Medic-Alert Foundation for patient enrollment forms so your at-risk patients can benefit from this emergency information network.

■ **Conduct health screenings** (i.e. blood pressure, glucose, cholesterol) free-of-charge or team up with a local physician's office. Donna Montemayor of HEB Pharmacy in Corpus Cristi, Texas organized a different health screening each day during National Pharmacy Week. For example, the pharmacy teamed up with a local podiatrist to provide free peripheral vascular disease screenings, publicizing the importance to diabetics and senior citizens. Montemayor was able to obtain sponsorship from a pharmaceutical company.

■ **Offer discount coupons or other incentives** for new or transferred prescription orders or to customers who turn in their outdated medications for disposal. The Polk

County Pharmacists Association spearheaded a campaign in Tampa, Florida that encouraged patients to bring in "dead meds." Anyone who brought in outdated medications was entered into a drawing for \$500, donated by the Association.

"Warm Up" with an October Hot Line

APhA is once again conducting a national toll-free hot line for consumers to call and talk to a pharmacist. This year, however, they're using the event as a "warm up" to National Pharmacy Week instead of part of the week's festivities. On October 6, from 9 am to 6 pm, APhA will join with the National Council on Aging (NCOA) to provide the "Dial-ogue on Pain Management for Older Adults." By calling (800) 789-1009, older adults and caregivers can speak to pharmacists and other experts about how to take charge of their pain. The purpose of the "Dial-ogue" is to make consumers more aware that the pharmacist is an important member of the health care team. Callers will be encouraged to talk with their local pharmacists with future questions.

APhA is making a free poster promoting "Dial-ogue" available to pharmacists. Call (800) 237-APhA for your free copy!

The Media as Your Ally

Reporters and editors are concerned with informing their public of events and issues that affect their publications's target audiences. For something to have news value, it must, in the eyes of the news media, have impact on the general community. If it is important to the public, it is important to the media.



Reproduce and distribute this Maryland Board of Pharmacy brochure for your patients as part of National Pharmacy Week and Talk About Prescriptions Month!

- No one, including physicians, can interfere with your freedom of choice of a pharmacy.
- It is not necessary that you buy your drugs from a particular pharmacy. However, since prepaid medical plans may require patients to acquire their prescriptions from select pharmacies, please become familiar with your plan.

IV. THE RESPONSIBILITY OF THE PUBLIC IS:

TO KNOW THE CONSEQUENCES OF FILLING OR WRITING A FORGED PRESCRIPTION

TO KNOW THE CONSEQUENCES OF ALTERING PRESCRIPTIONS

**TO KNOW THE CONSEQUENCES OF PASSING MEDICATIONS/
PRESCRIPTIONS ON TO PERSONS
OTHER THAN THOSE NAMED ON A
PRESCRIPTION**

V. WHERE TO GET FURTHER INFORMATION

- Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, Maryland 21215
- United States Pharmacopeia—
Advice for the Patient
Copyright—US Pharmacopeial
Convention, Inc. 1992
12601 Twinbrook Parkway
Rockville, Maryland 20852
- Maryland Pharmacy Act
Board of Pharmacy Regulations and
Drug Related Statutes and Regulations
Available from:
Maryland Pharmacists Association
650 West Lombard Street
Baltimore, Maryland 21201

- The Consumer Protection Division
200 St. Paul Street
Baltimore, Maryland 21202
- Elder-Health Program
University of Maryland
School of Pharmacy
20 N. Pine Street
Baltimore, Maryland 21201
- Public Libraries
- Poison Control—528-7701
1-800-492-2414
- Maryland Society of Hospital
Pharmacists
720 Light Street
Baltimore, Maryland 21230
- It is very important that you stay in
contact with your physician, pharma-
cist, or other health care provider.



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Your Right To Know About Prescriptions

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At one time or another, most of us will find it necessary to use medications. The common perception is that these medications, whether prescribed by a health practitioner, or obtained over the counter (prescription not required), will make us feel better if not cure us entirely. In 1992 over \$20 billion was spent on prescription drugs, and another \$8 billion on non-prescription drugs. Studies show, however, that up to 50 percent of all prescriptions are taken incorrectly. Pharmacists are available for counseling and providing information about drug usage, interactions with food or other drugs, and side effects. There is a grave need for a straightforward objective guide to drugs that cautions and informs the consumer about prescription drugs as a part of medical care.

This pamphlet is designed to help consumers become aware of their rights as patients receiving medication.

I. HOW TO GET THE BEST PHARMACEUTICAL SERVICE AVAILABLE

- Medication needs may vary—when and what drugs you need should dictate when and where to buy.
- Not all pharmacies are the same although the same quality is assured in so far as prescription filling is concerned.
- Some services vary from pharmacy to pharmacy such as home delivery, credit arrangements, hours of service, facsimile machines and discount prices. Choose the pharmacy that offers you the services you desire.
- Generic substitutes for trade name drugs are available in many cases upon your request. Please discuss this option with both your physician and pharmacist.

- All pharmacists have the same license to practice. Each person is responsible for the services they provide. Pick your pharmacist the same as you would your doctor, dentist or other professional.

- Ask your friends, relatives and colleagues about the pharmacies in your area. See what they like and dislike and compare that information with your needs and desires.

- Please tell your pharmacist about your drug history including allergies and any special problems you may have regarding your medications.

- Be sure you understand the label completely—do not leave the pharmacy until you know exactly what to do.

II. CLINICAL INFORMATION ABOUT THE DRUG(S) YOU WERE PRESCRIBED

- Do they have any side effects that you need to inquire about?

- Are there any special cautions about their use?

- Are you at any special risk because of your family history, drug history, etc.?

- What effect might this drug therapy have on pregnant or nursing women?

- Are there significant drug interactions related to your drug regimen or diet?

- Is there a potential for this drug to be habit forming?

- Are there any special precautions necessary relating to activities such as operating machinery while taking this drug?

III. WHAT ELSE IS IMPORTANT BEFORE, DURING AND AFTER TREATMENT WITH MEDICATIONS

- If you get home and realize you have forgotten or don't understand what you were told—CALL BACK AND ASK AGAIN.

- Report any changes in yourself that may be related to your medication to your doctor or pharmacist.

- Never take any one else's prescription medication.

- Insist on answers from each of your health care providers, physicians and pharmacists alike.

- You should expect prompt, courteous service—you should receive pertinent information as well as your drugs.

- Your pharmacist should show necessary concern for your drug related problems.

- Know how long your medications are good for, as well as how and when to dispose of them.

- Be aware of how to store and travel with prescription medications—this may alter their effectiveness.

- Tell each physician you see of medications you have received from other physicians.

- If you visit more than one pharmacy for drugs, be sure to tell the pharmacist about the other drugs you take.

- Ask your pharmacist if he/she maintains patient drug profiles. They may be helpful in avoiding problems with drug interactions, etc.

- According to the law, pharmacists are required to quote prescription prices over the phone.

The essential elements of real news are timeliness, news value, local appeal and interesting subject matter. Ask yourself these questions about your subject matter:

1. What is the significance of your pharmacy's services or special events to the general public?
2. How does your expertise, special event, or unique service help the community?
3. Are there trends in society that are reflected in your pharmacy? Can you capitalize on a trend as part of a National Pharmacy Week event? (for example, has your pharmacy stopped selling tobacco products?). You may want to consider conducting your own version of the "Great American Smokeout" and educate your patients about the health risks of smoking, as well as smoking cessation options.
4. When health news breaks, is there an angle related to your pharmacy or to the profession in general? Are you an expert in that area? (for example, if new research on diabetic treatment is publicized, does your pharmacy specialize in counseling/providing additional services for the diabetic patient?).

There are several kinds of coverage: *News* -- usually noting conflict or change; *Features* -- usually stories of human interest or news that is not time limited; *Editorial* - usually coverage by the media that takes a stand on an issue of relevance to the general public or to a particular constituency; and *Op-Ed* -- also opinion oriented, but generated by people not associated with the media.



Getting Started

Pharmacists play a role in delivering health care to almost every American. Health care is one of the hottest topics covered by the media these days; however, pharmacy does not always factor into the media's coverage. Reporters and editors are constantly covering the pharmaceutical industry, physicians, and hospitals, but many times overlook the contributions of the pharmacists, who are an integral part of the health care system.

In the minds of many reporters and consumers, the pharmacist is secondary to the medication - simply a dispenser. For this reason, every pharmacist has a big job to do to change that perception.

Americans take for granted the services provided by the pharmacist because they have always received the advice and care of their pharmacist without an appointment or being billed for that service, unlike the care provided by a physician or hospital. The media can be an important player in establishing the expertise of the pharmacist, but only when a pharmacy is offering the level of service and quality care that makes a difference in their

patients' health care.

Get started by reading the publications that you'd like to see cover your issues, watching and listening to news broadcasts and by becoming familiar with the reporters covering health care. After doing this, you will easily be able to develop a list of media targets.

Cut the job down to your size. If you only have one day a month to work on your public relations program, you need to set your sights for a small-scale result. If your stories are local, concentrate only on local media. If your story warrants regional or national coverage, be prepared to give your campaign quite a bit more time.

If you are concentrating your public relations program in a small local area, you should be able to develop a media list by calling the newspapers, television, and radio stations in the community and inquiring about the reporters who cover the health "beat." Remember, there are many more news outlets at your disposal than you might think. Don't overlook these important sources:

- Television stations have local news programs, editorial opinions and "talk back" opportunities, public affairs programs, one-on-one interview shows and public affairs "specials."
- Community cable stations can offer local news programming, community access channels, and public affairs programming;
- Public television stations provide local news programming as well as a diverse mix of locally produced public affairs programming;
- Radio formats include all-news stations, radio talk shows, public affairs programming, and editorial comment; and
- Newspapers have numerous "beat" reporters covering specialized issues for the main news section, editorial page editors, op-ed (opinion) pieces, letters to the editor, the business section, consumer reporters, and "style" sections offering soft news.

Here are a number of ideas and projects for you to use in preparing for the "National Pharmacy Week" and "Talk About Prescriptions Month" campaign. While some may seem almost impossible for a busy practice, bear in mind that good public relations takes time and cannot be accomplished overnight.

- Select a media liaison within your pharmacy to contact the media with the news release, fact sheets, radio public service announcements (PSAs) and an OP-Ed and other articles -- localize the provided samples. Provide the camera-ready logo and print media PSAs for easy publication. Also provide the media with any brochures or patient handouts you may be using to give them medication facts and an understanding of the kind of information pharmacists provide to the community.

■ **Radio station tie-ins** can provide a tremendous amount of exposure, including public service announcements, paid advertising, on location broadcasts, and news coverage. Radio stations frequently cosponsor promotions with community groups. For example, if your pharmacy can set up a free blood pressure or diabetes screening in a public place, it may be possible to get a station to promote use of the service during National Pharmacy Week.

Station tie-ins can be generated by writing to the station manager, describing why the promotion is in the public interest, and how the station can help. Furthermore, if your event offers a helpful community service, contact local television stations. Community service stories, especially with a good visual angle, have an excellent chance of being covered. You may also try for a listing in a local TV station's community billboard.

■ **Publicity, publicity, publicity!** Post information about your events in high traffic locations and where you can reach your target audience. Rely on the media as a prime information outlet; however, you should have other options as well. Even if a newspaper promises to publicize your event, there's always "Murphy's Law." A late-breaking story may "bump" the publicity of your event. Norma Vianzon of Eckerd Drug in Lakeland, FL suggests additional ways to increase patient turnout for promotions. For example, to supplement flyers in pharmacies and notices in newspapers, she will post information in libraries and at apartment and condominium complexes. Other locations to consider include neighborhood health centers, community centers, and the YMCA and YWCA. If targeting the elderly, try senior centers and retirement communities.

■ **Hold a luncheon, dinner, or reception**, sponsored by the pharmacy department, for other health profes-

sional colleagues. Pat Pellerin, director of pharmacy at Sunbelt Regional Medical Center in Houston, Texas, hosts a reception during National Pharmacy Week each year so staffers can get together and learn what pharmacists do. A videotape that explains pharmacists' duties and responsibilities runs continuously in the hospital lobby. Or hold the event just for the pharmacy employees to recognize their service throughout the year.

■ **Hold a forum for other health care professionals** to share information and to encourage more coordination among health care professionals in the community. The Brevard County Pharmacists Association in West Melbourne, Florida, organized an "HIV Forum for Area Health Professionals."

An Invitation

These are just a few of the many ways in which you can work to increase your visibility and professional

Resources for Promoting Pharmacy

National Sources for Patients and Providers

American Cancer Society	(800) 227-2345
American College of Allergy and Immunology	(800) 842-7777
American Diabetes Association	(800) 232-3472
American Dietetic Association	(800) 366-1655
American Heart Association	(800) 242-8721
American Lung Association	(800) 586-4872
American Red Cross	(202) 737-8300
Arthritis Foundation	(800) 283-7800
Epilepsy Foundation	(800) 332-1000
Juvenile Diabetes Foundation	(800) 233-1138
Medic-Alert Foundation	(800) 432-5378
Mothers of Asthmatics	(703) 385-4403
National AIDS Information Clearinghouse	(800) 458-5231
National Cholesterol Education Program	(301) 251-1222
National Council on Aging	(800) 424-9046
National Institute on Drug Abuse	(800) 622-4357
National Kidney Foundation	(800) 228-4483
National Osteoporosis Foundation	(202) 223-2226
National Stroke Association	(800) 787-6537
Poison Prevention Council	(301) 504-0580

standing in the community. If you launch, plan or are involved in any public relations campaign that you would like to share with MPhA members, send us a photograph of you involved in the activity along with a brief description of what you did and how you did it, and we will feature you in an upcoming issue of *The Maryland Pharmacist*.

Happy Promotions!

R

Editor's Note: This article was developed using materials supplied by the National Council on Patient Information and Education and the American Pharmaceutical Association. Special thanks are due to their exceptional efforts to enhance the public's perception of pharmacists as information specialists.

Continuing Education Quiz

September 1994 -- Poison Ivy/Part II

This month's questions are taken from the article on poison ivy that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. Members should enclose payment of \$5.00 (non-members \$10.00). The completed quiz for this issue must be received by March 30, 1995. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

Social Security Number _____

Address _____

City/State/ZIP Code _____

1. OTC products containing colloidal oatmeal to treat poison ivy dermatitis are claimed to provide all of the following actions EXCEPT:
 - a. temporarily protects skin.
 - b. relieves minor irritation.
 - c. dries oozing and weeping.
 - d. relieves minor itching.
2. OTC colloidal oatmeal products to treat poison ivy dermatitis must warn consumers to consult a doctor if the condition does not respond within:
 - a. 3 days.
 - b. 7 days.
 - c. 10 days.
 - d. 14 days.
3. The recommended strengths for sodium bicarbonate to treat poison ivy dermatitis are:
 - a. 1 to 100 percent.
 - b. 5 to 10 percent.
 - c. 10 to 25 percent.
 - d. 25 to 50 percent.
4. All of the following statements about the hyposensitization procedure used in patients with recurrent, severe poison ivy dermatitis are true EXCEPT:
 - a. both oral and intradermal administration can be used.
 - b. urushiol is the substance administered.
 - c. complete sensitization is usually accomplished.
5. All of the following ingredients of topical products are classified as counterirritants EXCEPT:
 - a. camphor.
 - b. eucalyptus.
 - c. menthol.
 - d. phenol.
6. Of the following, which is correct advice for a person using colloidal oatmeal as a soak for poison ivy dermatitis?
 - a. Sprinkle it under the tub's faucet into running warm water and stir before entering the tub.
 - b. Rub it on before entering the tub.
 - c. Wipe it all off with a towel after getting out of the tub.
7. Local anesthetic are thought to inhibit the conduction of impulses stemming from sensory nerves by altering neuronal cell membrane permeability to:
 - a. calcium.
 - b. prostaglandins.
 - c. sodium.
 - d. water.
8. The least desirable dosage form of local anesthetic to use for poison ivy dermatitis is the:
 - a. cream.
 - b. gel.
 - c. lotion.
 - d. ointment.
9. The effectiveness of hydrocortisone in treating poison ivy dermatitis is due to its ability to:
 - a. antagonize the inflammatory response.
 - b. dry oozing and weeping associated with blistering.
 - c. inhibit histamine receptors.
 - d. provide local anesthetic action.
10. The route of administration that is approved for OTC antihistamines when used to treat poison ivy dermatitis is:
 - a. oral.
 - b. parenteral.
 - c. topical.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION, organized in 1926, meets every third Wednesday of the month at Horn and Horn Smorgasbord on Cromwell Bridge Road, Belway Exit 29. Visitors are welcome. Call John Ayd at (410) 661-2383 for details.

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Have something to sell, rent, or trade? Need a pharmacist? Looking for a new position? MPhA members can place a classified ad in *The Maryland Pharmacist* and reach more than 1,400 pharmacists for free. MPhA will remove member ads after six months unless otherwise notified by the member.

Non-members may also place a classified ad. The ad placement charge is \$10 for a maximum of 50 words plus 50 cents per word greater than 50.

To place an ad, send your typewritten copy to MPhA, 650 West Lombard Street, Baltimore, MD 21201-1572. Or you can FAX your ad to (410) 727-2253.

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PHARMACY FOR SALE located in a medical building. Good location with parking. Medical supplies and surgical support stockings account for 65% annual income. This store has a lot of potential for the right person and it is priced for a quick sale, only \$175,000. Phone (301) 474-5151.

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(410) 727-0746
(800) 833-7587 toll-free
(410) 727-2253 FAX

Mid-Atlantic DUR, Inc.

(410) 727-6122
(800) 833-7587 toll-free

Maryland Board of Pharmacy

4201 Patterson Avenue
Baltimore, MD 21215
(410) 764-4755
(800) 542-4964 toll-free

Maryland Division of Drug Control

4201 Patterson Avenue
Baltimore, MD 21215
(410) 764-2890

MSHP Offices

(410) 752-3318

UMAB School of Pharmacy

(410) 706-7650

American Pharmaceutical Association

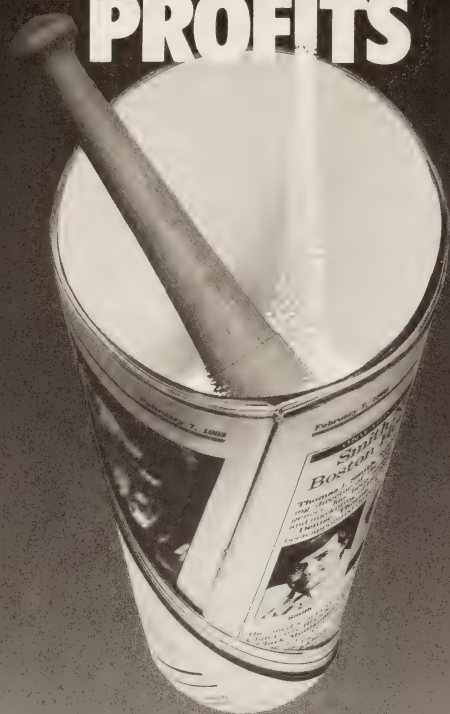
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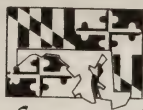
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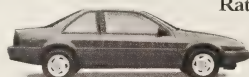
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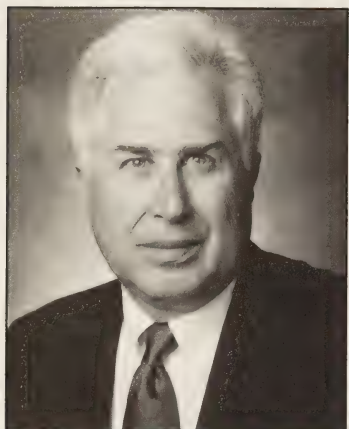
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President's Commentary

Arnold Davidov, P.D., 1994-1995 MPhA President



In the latest issue of the University of Maryland School of Pharmacy Alumni newsletter, Dean Knapp devoted his "Commentary" to some observations about the restructuring of pharmacy in a reformed health care system. Dean Knapp states "MPhA, with the help from the School of Pharmacy, should be out in front with ways in which pharmacy can help health care reforms design a system to improve the use of drugs in patients, meet the goals of cost management and provide pharmacists a share of the savings generated."

I am happy to report that we take this challenge seriously. The Association has formed a Pharmaceutical Care Committee itself chaired by MPhA Trustee and employee pharmacist Tim Lubin. This Committee has several responsibilities and goals. Two of those charges focus on providing education about the concept and application of "pharmaceutical care" -- the system of providing complete support and management of patients' drug therapy. Pharmaceutical care, as envisioned by its creators, would have pharmacists taking responsibility for the therapeutic outcomes of drugs and their affects on patients.

MPhA plans to concentrate on two areas over the next several months -- pharmaceutical care education and pharmacist service reimbursement.

The first area includes offering very targeted, very intensive continuing education programs on specific therapeutic issues (e.g. asthma, diabetes, hypertension). These programs will be markedly different from previous CE seminars as they will involve small interactive workshops where pharmacists will work with the presenters and each other. An integral part of each of these programs will be a review of the pharmaceutical care concept and a full overview of how the concept is applied to each specific therapeutic issue. I believe that these programs, although not the kind of seminar for everyone, will be a major step forward to helping pharmacists implement pharmaceutical care.

In addition, we are working with representatives from the School of Pharmacy to make the non-traditional Pharm.D. program, "Introduction to Pharmaceutical Care," available to as many pharmacists as possible. Although final details have not been worked out, this may take the form of an MPhA certificate program based on the School's existing curriculum.

The second area involves the creation of a continuing education program to be offered through MPhA's affiliated and recognized organizations. This program, coordinated with NARD, will show pharmacists how to begin documenting and billing for those pharmacist services we currently provide -- intervening on drug/drug interactions, potential compliance problems, and others. MPhA recognizes that all pharmacists have been doing at least an elementary level of pharmaceutical care. Now we have to learn how to document and bill for that level before moving on to the next.

Details about these programs will appear in special mailings to members and in future issues of *The Maryland Pharmacist*. I hope that you will take advantage of these programs as MPhA works with you and others to advance the profession.

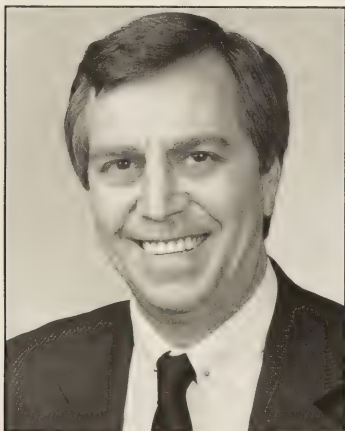
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New Drugs in 1994 -- Part I

Overview of Drugs for AIDS

Thomas A. Gossel, R.Ph., Ph.D., Dean, Ohio Northern University

J. Richard Wuest, Pharm.D., Professor of Pharmacy Practice, University of Cincinnati



This educational program is made possible through a grant-in-aid from

SEARLE

This lesson begins a multi-part discussion of the 39 new drugs approved by FDA or marketed since 1993.

When each drug is presented, it will be followed by a (1P) or (1S). These notations refer to whether the Food and Drug Administration, in its review of the New Drug Application, classified the drugs as warranting priority (1P) or standard (1S) consideration. When there is no notation, the product described is a biological and the FDA review process is different from the one used for drugs.

The (1P) signification represents a drug, which, in FDA's opinion, is an advancement in therapeutics sufficient to be brought through the approval system and to the market for availability to patients as quickly as possible.

Drugs are given the (1P) rating when there is no effective drug available in the U.S. for the indicated condition; the drug is more effective than currently available drugs; or, there are important advantages over drugs already marketed (i.e., fewer side effects, less potential for drug interactions, less frequent dosing regimen, etc.).

Drugs that are coded (1S) are considered to be similar to other drugs already marketed. While they may be better for a subpopulation of patients with the condition being treated, these drugs do not represent a significant therapeutic advance for the overall target patient population.

Drugs For AIDS Patients

Atovaquone (1P) - Trade name: Mepron, 250 mg tablets

Atovaquone is an antiprotazoal agent similar to chloroquine. It has activity against *Pneumocystis carinii* by inhibiting the enzyme activity of the organism. The drug concentrates within the organism's acid vesicles and raises the Ph. This "non-weak base effect" results in inhibition of the parasite's growth.

Pneumocystis carinii is one of the most dangerous opportunistic organisms that invade and cause morbidity in immunocompromised (AIDS) patients. The organism reportedly causes a pneumonia in approximately 80 percent of patients with AIDS and is the leading cause of death in these individuals.

While sulfamethoxazole-trimethoprim (SMZ-TMP) and pentamidine (Pentam) are the agents of choice for treating *Pneumocystis carinii* pneumonia (PCP), some patients can not tolerate or do not respond to therapy with these agents. Atovaquone is an alternate for treating PCP in this group of patients.

All three of the above agents can cause serious side effects, but some patients can tolerate those of one drug versus the other two. In one comparative study, nine percent of patients dropped out due to side effects from atovaquone, versus 24 percent who could not tolerate SMZ-TMP. The most common side effects with atovaquone were rash (24

percent), nausea (21 percent), vomiting (14 percent), diarrhea (19 percent), headache (16 percent), fever (14 percent) and insomnia (10 percent).

The effectiveness of atovaquone, SMZ-TMP and pentamidine is said to be approximately the same, 60+ percent survival for eight weeks. When compared to SMZ-TMP, the failure rate from lack of response was higher with atovaquone treated patients (17 versus six percent) but the failure rate due to adverse effects was significantly higher for SMZ-TMP treated patients (20 versus seven percent).

There was a higher mortality rate in patients treated with atovaquone (eight percent) versus SMZ-TMP (three percent) during the three week treatment courses and 8 week follow up. This was reputed to be due to increased bacterial infections causing death in atovaquone-treated groups since its spectrum of activity is much less than SMZ-TMP.

The dose for Mepron is three tablets three times a day with food (2,250 mg daily) for three weeks. It is important to take atovaquone with food. Taking the tablets with meals (especially those containing at least 23 grams of fat) improves absorption significantly, potentially increasing bioavailability by 300 percent.

One interesting point on the cost of Mepron is that its manufacturer has announced a plan that places a cap on what the patient/third party program will have to pay for the drug. After the patient's dosing reaches 41 grams in a 12-month period, the manufacturer will pay pharmacists directly. Information on this program is available by calling (800) 443-6763. A patient information booklet is available from the same 800 number.

No drug interactions have been seen with atovaquone. Since it is highly protein bound, the possibility of affecting other highly protein bound drugs exists.

Goals

The goals of this lesson are to identify and discuss new drugs recently introduced to the marketplace, with special emphasis given to anti-infectives and drugs indicated for patients with AIDS.

Objectives

At the conclusion of this lesson, successful participants should be able to:

- Exhibit knowledge of the pharmacologic classification and therapeutic considerations for each of the drugs discussed;
- Select from a list, the indications, mechanisms of action, benefits and limitations of drugs discussed;
- Identify adverse effects, major toxicities, and drug interactions associated with the drugs; and,
- Demonstrate an ability to counsel patients on these new drugs.

CE Credits

To earn continuing education credits for this article, complete the CE Quiz on page 30 and follow the instructions at the top of the page.

Rifabutin (1P), Trade name: Mycobutin, 150 mg capsules

Rifabutin, as its name suggests, is similar to rifampin both chemically and pharmacologically. These drugs, the rifamycins, appear to act by inhibiting DNA-dependant RNA polymerase. This has not yet been proven, but the drugs do interfere with the ability of susceptible organisms to synthesize the proteins they need for replication.

Unlike rifampin, rifabutin is not

very active against *Mycobacterium tuberculosis*. Therefore it should not be used in patients with TB since it may lead to resistance against rifampin.

Rifabutin is indicated for prophylaxis against disseminated *Mycobacterium avium* infections in patients with advanced HIV infections. It is the first drug to be approved for this indication. *Mycobacterium avium* is an opportunistic organism that is deadly to AIDS patients.

It is estimated that 40 percent or more of patients with advanced AIDS infection develop disseminated *Mycobacterium avium* complex (MAC) infections which are difficult to treat, requiring multiple drug therapy. Therefore, it is believed that rifabutin is of benefit for HIV patients in preventing MAC infections or decreasing their incidence and severity. Prophylactic use of rifabutin is considered worthwhile by many experts.

Rifabutin is reasonably well tolerated by most patients. However, twice as many patients in a clinical study dropped out because of adverse reactions as compared with placebo (16 versus eight percent). Major reasons for drop out were rash (four percent) and gastrointestinal tract upset (three percent).

Like rifampin, rifabutin discolors urine, saliva, sputum, tears and sweat to a brown to red-orange color. The potential for it discoloring contact lenses exists, but has not been reported.

Rifampin is linked to many drug interactions because it is a potent enzyme inhibitor. While these interactions have not been reported for rifabutin, they have not been studied either, so the potential exists. Several drugs have been reported to interact with rifampin, and, possibly rifabutin. They follow.

1. **Rifampin may antagonize anticoagulants.** Rifampin increases the metabolism of warfarin-type anticoagulants



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(Coumadin, etc.) and markedly reduces their effect in most patients. If both agents must be given to the same patient, prothrombin time blood tests should be performed frequently to determine whether anticoagulant dosage adjustments are needed. Patients must be convinced that strict compliance with the dosage schedule of each drug is imperative.

2. **Rifampin antagonizes oral contraceptives.** Rifampin can decrease the contraceptive effectiveness of both estrogens and progestins by increasing their metabolism via enzyme induction. The manufacturers of these drugs state that the reliability of oral contraceptives may be adversely affected by rifampin; and that reduced efficacy and increased incidence of breakthrough bleeding have been associated with concomitant use. When rifampin is added to the therapy of women who desire contraception protection, another nonhormonal method of birth control should be

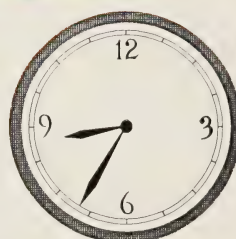
recommended.

3. **Rifampin may antagonize corticosteroids.** Rifampin may antagonize the activity of corticosteroids by increasing their hepatic metabolism. The manufacturers of both drugs state that rifampin may enhance metabolic clearance of corticosteroids and decrease their blood levels and physiological activity. While there is no contraindications to their concomitant use, when there two agents are given together the patient should be monitored for inadequate corticosteroid may have to be increased, possibly doubled.
4. **Rifampin may antagonize cyclosporine.** Rifampin may reduce blood levels of cyclosporine (Sandimmune) and thereby decrease its immunosuppressant activity. The most likely mechanism for this interaction is rifampin-induced hepatic metabolism of cyclosporine. Its manufacturer states that monitoring of plasma levels of cyclosporine and dosage

adjustments are essential if these two drugs are given together.

5. **Rifampin may antagonize digitoxin.** Rifampin may antagonize the activity of digitoxin presumably by increasing its hepatic metabolism via enzyme induction. The manufacturers of rifampin state that it may decrease the effects of digitalis preparations. The manufacturers of digitoxin advise against concomitant use of enzyme inducers. Digoxin does not appear to be as affected and it may be a better alternative in patients needing a digitalis glycoside and rifampin.
6. **Rifampin may antagonize quinidine.** Rifampin may increase the metabolism of quinidine and thereby decrease its activity resulting in a loss of cardiac arrhythmia control. While manufacturers of these agents do not mention the potential for this interaction in their product labeling, many authorities state that rifampin is likely to reduce the effects of quinidine in the majority of patients. They further

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recommend quinidine plasma level determinations during concomitant use to assure therapeutic effects. A similar interaction has been reported for disopyramide, but not for other antiarrhythmic drugs which could be considered as alternative therapy.

7. Rifampin may antagonize verapamil.

Rifampin may antagonize verapamil by increasing its metabolism possibly leading to a loss of effectiveness. Manufacturers of both drugs warn about the interaction in their package insert. There is a lack of documentation that other calcium channel blockers are affected similarly, but it is suspected that they would be. If the patient needs both rifampin and a calcium channel blocker, higher than normal doses of the calcium channel blocker may be required.

8. Rifampin may antagonize xanthines.

Rifampin may decrease serum theophylline levels and antagonize its therapeutic effect. The proposed mechanism for this interaction is increased hepatic metabolism. Manufacturers of both drugs warn that patients taking theophylline be monitored for possible dosage adjustment when rifampin is added to or discontinued from therapy.

The recommended dose for rifabutin is 300 mg once daily. Food may slow, but does not reduce the extent of absorption. Therefore, in patients who experience GI upset, the dosage can be adjusted to 150 mg twice a day with food.

The manufacturer of Mycobutin is offering a patient assistance program similar to those of other AIDS-related drugs.

Trimetrexate (1P) - Trade name: NeuTrexin, 25 mg vial

Trimetrexate is a derivative of methotrexate. It has been approved initially for use as a second line treatment for mild to moderate

Pneumocystis carinii pneumonia (PCP) in AIDS patients who do not respond to or are intolerant of the first line agents. As stated earlier, these are sulfamethoxazole-trimethoprim (SMZ-TMP), pentamidine and atovaquone. Trimetrexate is the first drug to be approved for treating severe PCP.

Even though it is a derivative of methotrexate, trimetrexate is claimed to be a "lipophilic" antifolate agent. This means that unlike methotrexate, it can penetrate both human cells and organisms like *Pneumocystis carinii* by passive diffusion rather than the reduced folate transport system.

Trimetrexate is a potent inhibitor of dihydrofolate reductase in bacterial, protozoal and mammalian cells. This is an important enzyme in the folate coenzyme biochemical pathway. The inhibition of folate coenzymes prevents the biosynthesis of thymidylate, an essential component of DNA. Trimetrexate also inhibits purine biosynthesis indirectly by depleting reduced folate with subsequent inhibition of formyl transferase. Both of these actions inhibit DNA and RNA synthesis.

It is imperative that leucovorin be coadministered with trimetrexate and for 72 hours post-treatment to protect normal cells from toxic effects. Leucovorin is the antidote for methotrexate toxicity (methotrexate rescue). With trimetrexate therapy, leucovorin helps protect bone marrow, liver, gastrointestinal and kidney cells. This is because leucovorin enters human cells via the reduced folate transport carrier system to protect them. *Pneumocystis*

carinii do not have this transport mechanism so the trimetrexate enters and destroys the organisms.

In humans, without leucovorin, serious and life-threatening bone marrow suppression, oral and gastrointestinal mucosal ulceration and renal or hepatic dysfunction can occur. Patients should have blood tests at least twice a week while on trimetrexate to assess hematology, renal function and hepatic function.

In clinical trials, the responses to trimetrexate and SMZ-TMP were in excess of 50 percent. Response, in this instance, was defined as alive and off ventilation support. However, as with atovaquone, mortality in the trimetrexate group was about twice that of SMZ-TMP (27 versus 16 percent). Again, this was thought to be due to the lack of activity of trimetrexate against other opportunistic organisms that can kill AIDS patients. The patients who failed therapy due to toxicity were significantly fewer with trimetrexate as compared to SMZ-TMP.

Trimetrexate continues to be studied for potential use as an antineoplastic drug in treating colorectal, lung, and prostate cancers, and possibly rheumatoid arthritis.

The intact vials of NeuTrexin should be refrigerated. Once properly reconstituted, trimetrexate solution is reported to be stable for at least 7 days at room temperature or under refrigeration. The dose is 45 mg/m² intravenously once daily over 60 to 90 minutes. Infusions can be prepared with 5 percent dextrose in water (D5W), but not normal saline solution (NSS). When mixed with

AIDS Drugs Marketed 1993-94

Drug	Trade Name	Classification
Atovaquone	Mepron	Antiprotazoal
Rifabutin	Mycobutin	Antibacterial
Trimetrexate	NeuTrexin	Antiprotazoal
Zalcitabine	Hivid	Antiviral - HIV

Table One

chloride salts, trimetrexate can precipitate out of solution.

Zalcitabine (1P) - Trade name: Hivid, 0.375 and 0.75 mg tablets. Zalcitabine, also known as dideoxycytidine (ddC) is the third synthetic nucleoside analog to be approved for HIV infections. The previous two analogs are zidovudine (Retrovir/AZT) and didanosine (Videx/ddI).

Zalcitabine is indicated for treatment of patients who are resistant to or intolerant of zidovudine, or who have experienced significant clinical or immunological deterioration with zidovudine therapy. In premarketing trials, patients have displayed increased CD4 cell counts which suggests overall improvement in their disease.

Unfortunately, at press time, there were no definitive data regarding progression of HIV infection, or upon reducing the incidence of opportunistic infections. Nonetheless, there is evidence that combination therapy with zidovudine and

zalcitabine may work better than either drug alone to increase (T-helper cells) to higher levels in patients with advanced AIDS.

Zalcitabine is converted intracellularly into dideoxycytidine triphosphate, its active metabolite. Its mechanism of action, like that of AZT and ddI, is to inhibit reverse transcriptase, an enzyme required by HIV to replicate.

Even though the alternate use of zalcitabine with zidovudine has not been approved, there are some physicians who believe that this type of therapy may reduce side effects and lessen the chance of resistance to drug therapy.

The toxicity of greatest concern with zalcitabine is peripheral neuropathy which has occurred in 17 to 31 percent of patients in clinical trials. It is characterized by a burning sensation and numbness of the fingers and/or toes. These can become progressively worse and more painful, and may be irreversible if the drug is not discontinued in a timely manner.

Drugs that can also cause

peripheral neuropathy should be avoided if possible in patients receiving zalcitabine. These include chloramphenicol, gold salts, hydralazine, isoniazid, metronidazole, nitrofurantoin, phenytoin and vincristine.

Other rare toxicities associated with zalcitabine are adverse cardiac effects, anaphylactic reactions, congestive heart failure and esophageal ulceration. Side effects at the 5 percent or higher level are: oral ulcers, headache, rash, fatigue, nausea, anemia, itching, and muscle pain.

The bioavailability of zalcitabine when administered orally is greater than 80 percent. When taken with food the rate and extent of absorption are reduced, but the clinical significance of this is not known.

Recommended dosing for most patients is 0.75 mg zalcitabine with 200 mg zidovudine (Retrovir) every eight hours. Since the drug is eliminated primarily by the kidneys, patients with impaired renal function should receive the lower dosage. **R**

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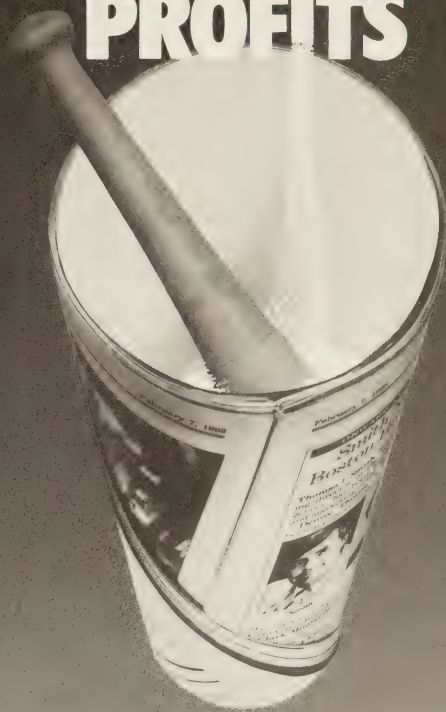
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Pharmaceutical Care and the Death Chamber

An Ethical Dilemma for Pharmacists

Raymond C. Love, Pharm.D.



Earlier this year, convicted murderer John Thanos became the first person executed by the state of Maryland in more than 20 years. Having failed to select a method of execution, Mr. Thanos was the first Maryland prisoner to die by lethal injection.

Mr. Thanos' sentence was carried out by a prison guard. The guard started intravenous lines in the prisoner's left and right antecubital spaces and administered a dose of thiopental sodium calculated to put Mr. Thanos asleep. The thiopental was followed by a dose of pancuronium bromide to prevent coughing and involuntary muscular contractions which might have made the witnesses to the execution uncomfortable. Finally, the guard administered a dose of potassium chloride in order to induce asystole and bring about death from cardiac arrest. The Department of Public Safety has not disclosed the source from which these drugs were obtained or whether a pharmacist was involved in their procurement or preparation. They have also not revealed the details of any accommodations reached with the federal authorities regarding transfer of controlled substances.

*Should a pharmacist
knowingly participate in an
execution in any manner?*

This past session, the Maryland State Legislature passed a bill establishing lethal injection as means of execution for condemned prisoners in this state. The bill also contained a provision which permits pharmacists to dispense these drugs for use in executions without a prescription.

While the legal issue regarding controlled substances is of interest to pharmacists, a much more important issue must be considered: Should a pharmacist knowingly participate in an execution either as the provider of drugs for lethal injections or in any other manner?

A brief survey of my colleagues produces a wide array of responses. Some would "... welcome the opportunity to rid the world of that bastard..." Others insist that "...taking a life is wrong..." Once one gets past their gut feelings about Mr. Thanos and capital punishment, the dilemma still remains: Is it proper for a pharmacist to play a role in capital punishment?

While it's fine to argue hypothetically about this question, what would you do if a state official presented you with an order for the chemicals listed above (and appropriate documentation that you would be violating no law if you provided them)? What would you do if your were asked to provide information on compounding an intravenous solution, determining compatibilities or calculating a rate of administration for a lethal injection?

One could look toward their professional associations and the American Pharmaceutical Association Code of Ethics to answer this dilemma. Clearly, the code of ethics holds the "health and safety of patients to be of first consideration" and states that the pharmacist should not "condone the

....providing of drugs.... that lack therapeutic value for the patient." But neither the American Pharmaceutical Association or the American Society of Hospital Pharmacists (ASHP) prohibits pharmacist participation in lethal injection. ASHP has gone so far as to state that pharmacist participation in capital punishment is a matter of "individual conscience."

Traditional discussions of bioethics also lead to no single conclusion. Though some bioethicists include the sanctity of life as a cardinal principle, others consider only beneficence (do good), non-maleficence (do no harm), fidelity, veracity, autonomy and distributive justice as primary principles.

On first examination, the ethical principle of nonmaleficence or the Hippocratic doctrine of "Premum Non Nocere" (Above all else, do no harm) would seem to prohibit health professional participation in capital punishment. But some pharmacists familiar with the administration of the "executioner's cocktail" fear that small errors in its use could result in a patient slowly suffocating to death. They argue that pharmacist participation in an execution by lethal injection can help prevent "an agonizing" or "unmerciful death." Many have stated that health professional participation could have prevented the problems which occurred during the recent execution of serial killer John Wayne Gacy.

Other ethical concepts such as fidelity and beneficence are similarly unsatisfactory in providing a resolution to the issue. These principles can be interpreted with a view towards either the pharmacist's responsibility to the condemned or towards his/her responsibility to society.

While individuals must consider the relevant ethical principles, societal beliefs and professional doctrine, it is

ultimately one's personal values which will impact most heavily upon a decision to assist in taking a life. However, as a profession, pharmacy must take inventory of its own values and come to its own conclusions about capital punishment. The profession was caught napping when the legislature proceeded to "pencil us in" to this state's law on lethal injection without Maryland pharmacists having a more open debate about this issue.

As a citizen of Maryland, I've not yet fully decided whether capital punishment is right or wrong. However, as a pharmacist, I am convinced that our participation would be a grievous error. I didn't reach this conclusion by considering the sanctity of life, philosophical arguments or even man's potential for error; this conclusion is based on my aspirations for our profession.

Pharmacy is a profession which has been entrusted by society with the control of a potent group of chemicals. In exercising this control, pharmacists have developed a unique body of knowledge to insure that these agents are used in a safe, effective and optimal manner. Pharmacy seeks to be the *profession* which is responsible for seeing that patients get the most out of their drug therapy. In pursuit of this end, pharmacy has made this the era of "pharmaceutical care" and "cognitive services." Pharmacists are striving to elevate the status of the profession above that of mere providers of drugs. In the midst of these efforts, one must ask whether the profession should risk returning to the role of procurement without consideration of the purpose for which the procured chemicals will be used. Pharmacists must also decide whether utilization of this unique body of knowledge for a controversial and non-therapeutic purpose is consistent with the profession's efforts to elevate its status.

The American Medical Association is of the opinion that there is no role for physicians in capital punishment. The issue of lethal injection provides the profession of pharmacy with an opportunity to clarify its role not only in health care, but in society. **R**

Annotated Code of Maryland
Article 27
Crimes and Punishments

§ 71

(A) The manner of inflicting the punishment of death shall be the continuous administration of a lethal quantity of an ultrashort-acting barbiturate or other similar drug in combination with a chemical paralytic agent until death is pronounced by a licensed physician according to accepted standards of medical practice.

(B) The administration of the lethal substances required by this section may not be construed to be the practice of medicine and, notwithstanding any other provision of law, any pharmacist or pharmaceutical supplier may dispense drugs to the Commissioner of Correction or the Commissioner's designee, without a prescription, for the purpose of carrying out the provisions of this section.

About the Author

Raymond C. Love, Pharm.D., is Assistant Professor and Vice-Chair, Department of Pharmacy Practice and Science at the University of Maryland at Baltimore School of Pharmacy. He also serves as a School of Pharmacy representative to the University of Maryland at Baltimore Center on Biomedical Ethics.

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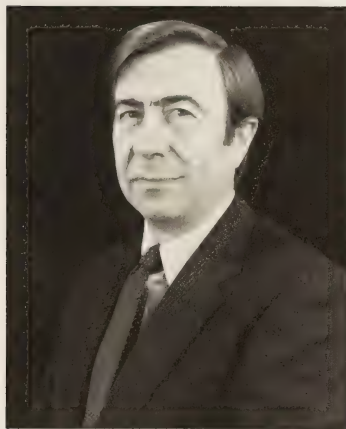
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An Update on Practitioner Education

Perspectives from the American Association of Colleges of Pharmacy

Richard P. Penna, Pharm.D., Associate Executive Director, AACP



In July, 1992, the American Association of Colleges of Pharmacy adopted policy that the entry degree for pharmacy practice awarded by schools and colleges of pharmacy should be the Doctor of Pharmacy (Pharm.D.) degree. The decision was reached after considerable discussion and debate. Following the decision, some practitioners expressed the view that all pharmacists who do not have a Pharm.D. degree should be granted one by their *alma mater*. Others expressed the belief that schools and colleges of pharmacy should make available academic courses to practitioners so that they may earn the degree without having to return to school full time. Some suggested that schools and colleges of pharmacy join with professional associations to provide education and training to pharmacists so that they may acquire the knowledge and skills needed to succeed in a changing health care system. Still others have proposed that the profession's organizations should develop a process of granting an "equivalent" Pharm. D. credential.

Academic pharmacy has responded to each of these suggestions with clear policy direction and programs. AACP policies state that the degree be awarded after completing a prescribed course of study that has been approved by the faculty of the university, school, or college; secondly, that practitioners must be provided opportunities to earn a Pharm.D. degree; thirdly, that the association supports the development of rigorous educational experiences developed by schools and colleges of pharmacy that prepare practitioners for new practice

roles; and fourth that the association supports the development within the profession of mechanisms that assess, validate, and certify practitioners' competencies at or beyond contemporarily defined levels for general practice of pharmacy.

The discussions, debate, and (in some cases) rancor concerning the degree that pharmacists should possess and the length of time it would take to earn the Pharm.D. has distracted attention from the real issue

AACP policies state that the degree be awarded after completing a prescribed course of study that has been approved by the faculty of the university, school, or college

confronting the profession—that in order to be successful in the health care market place, pharmacists will depend on what they know and what they can do, not on the initials that follow their names. The economic and social forces driving health care reform are changing the health care and pharmacy market places in profound ways. AACP's decision that the Pharm.D. must be the entry degree was based on a conviction that pharmacists will need knowledge and skills in considerable excess and in greater variety than those currently provided in existing entry degree programs (both B.S. and Pharm.D.).

The evidence for a changing pharmaceutical market place is already


apparent: the rapid increase in automated dispensing, the rise in the use of technical personnel in dispensing, the catastrophic squeeze on dispensing margins, the consolidation of hospitals, the combining of institutional pharmacy operations, and the overnight expansion of mail order dispensing all point to the undeniable conclusion that fewer pharmacists will be needed to dispense medication in the future. On the other hand, the growing recognition that pharmacists' managing patients' drug therapies result in major, cost effective improvements in patient care provide a clear vision of where pharmacists should concentrate their efforts and their learning in order to be a successful participant in the evolving health care market place.

More to the point, the growth in the numbers of Pharm.D.s in the profession will be evolutionary. However, market place demands for practice changes are revolutionary. The market will not wait until there are enough new Pharm.D. graduates. Current practitioners must prepare themselves (i.e., acquire new knowledge and skills) to take advantage of the new opportunities that the health care market place is presenting.

Nontraditional Education

The future of pharmacists' success lies in their abilities to manage their patients' drug therapies. They must have the knowledge and skills to do so. Schools and colleges of pharmacy are developing programs to assist practitioners to acquire them. These educational offerings are similar to those offered to full-time pharmacy students: they are rigorous, educationally sound, based on achieving predefined practice competencies, and associated with assessments of learning. Because these programs are offered to practitioner students outside the traditional pharmaceutical education locale, they are called nontraditional educational programs. Generally, these programs provide education through distance learning techniques such as videotaped lectures, interactive computer, or satellite television. AACP and pharmacy school faculty are exploring ways to make nontraditional education even more nontraditional. For example, educational experiences in which practitioners learn in their own practices, from their own patients are being used by several schools. Computerized, educational linkages between practitioner students and pharmacy school faculty are being tried by other schools. Through the SmithKline Beecham Foundation Grant Awards for Pharmacy Schools program, many schools are testing a variety of nontraditional educational modalities for practitioners.

Some schools have nontraditional educational programs which award a Pharm.D. degree to practitioners who complete them. Other programs offer practitioners the opportunity to enroll in specific academic courses or educational programs specifically designed to impart a defined set of practice competencies to practitioner/




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students. These latter courses are often called "certificate programs" because a certificate of completion is given to practitioners who complete the requirements of the programs.

The Formation of CAPE

In response to the desire of schools and colleges of pharmacy to change their curriculums to support the profession's vision of providing pharmaceutical care, the American Association of Colleges of Pharmacy organized the Center for the Advancement of Pharmaceutical Education (CAPE). CAPE has a number of charges among which is the charge to assist schools and colleges of pharmacy to develop and offer degree and nondegree nontraditional education to practitioners.

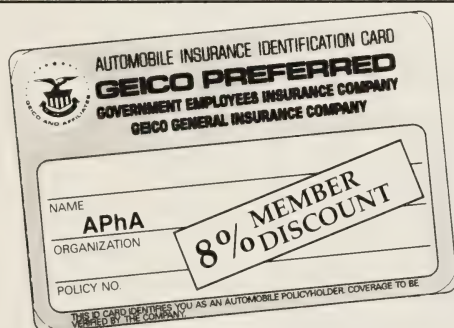
CAPE appointed an advisory panel of practitioners, educators, and staff of national pharmaceutical organizations. At its first meeting, the panel suggested that CAPE sponsor a national conference of schools that were implementing, planning, or interested in offering nontraditional educational programs to practitioners. The conference was held in May, 1994. Seventy-one attendees including faculty from 41 schools and colleges of pharm-

acy attended. The conference permitted those with experience in distance learning and nontraditional education to share their experiences with their beginner colleagues. Speakers from outside of pharmaceutical education discussed such topics of how adults learn, assessing and giving credit for prior learning (e.g., from experience), and the technologies possible for distance learning.

The conference stimulated a considerable amount of excitement among its participants which has continued. The group met during the July AACP Annual Meeting to update one another regarding their status in delivering or planning nontraditional programs. Currently, 24 schools of colleges offer a part-time Pharm.D. program to practitioners, and 12 schools or colleges offer a Pharm.D. program in a nontraditional format. An additional number of schools (about 20) are actively planning to offer or are studying offering a nontraditional Pharm.D. program.

A Credentialing System

Schools and colleges of pharmacy have the responsibility



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ibility to graduate students who are capable of practicing over a lifetime career in any of a myriad of pharmacy practice settings. Pharmaceutical education shares with the profession's practice associations the responsibility to provide programs that enable practitioners to remain competent and current with changing trends in health and pharmaceutical care. Many practitioners want their academic degrees to reflect a valid indication of their contemporary practice abilities. AACP believes that competency assessment is the best indicator of contemporary practice knowledge and skills. As a result, AACP supports a national, voluntary credentialing or certification system developed and managed by the profession that will indicate to the public, employers, peers, and other health professionals that holders of the credential or certificate possess the knowledge and skills to practice pharmacy as contemporarily defined through periodic scope of practice studies. Because credentialing is time-limited, it will assure currency. Because it is tied to contemporarily defined practice functions, it will be timely. Because it will consist of an assessment process, it will be diagnostic (i.e., what skills need to be developed, what knowledge needs to be acquired). Because it must be psychometrically sound, it will serve as a reliable and valid competence indicator to employers, patients, peers, and other professionals.

Conclusion

Managing patients' drug therapies is the present and the future of pharmacy practice. Schools and colleges of pharmacy are actively revising their curriculums to prepare students with the necessary knowledge and skills. Schools and colleges of pharmacy also are actively offering nontraditional educational programs to practitioners to assist them to improve their drug therapy management skills. Practitioners have an expanding choice of educational

programs to choose from that will meet their educational needs. Some are of sufficient rigor and length to award a Pharm.D. degree. Others, while shorter in duration and not resulting in a degree, provide knowledge and skills for specific practice functions.

AACP, through CAPE, is supporting and encouraging schools and colleges of pharmacy to increase the number and frequency of such nontraditional offerings (degree-granting and nondegree-granting). Moreover, AACP is encouraging the profession to investigate a voluntary credentialing system through which practitioners can be certified as meeting contemporarily defined standards of general pharmacy practice.

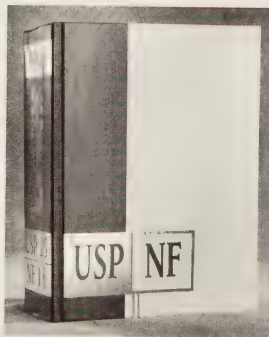
If the future of the profession lies in managing patients' drug therapies, the future of individual practitioners lies in possessing the knowledge and skills to manage drug therapy in individual patients. R

About the Author

Richard P. Penna is Associate Executive Director of the American Association of Colleges of Pharmacy. AACP represents the interests of the more than 75 colleges and schools of pharmacy in the United States. For additional details, contact Dr. Penna at the American Association of Colleges of Pharmacy, 1426 Prince Street, Alexandria, Virginia 22314.

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1. Outpatient prescription medicines account for approximately what percent of total health care spending?
a. 5% b. 10% c. 15% d. 20%
2. How many years of patent life typically remain once a new drug is approved for marketing?
a. 17 b. 10-12 c. 3-5 d. 5-7
3. Which amount is the closest to the actual cost of dispensing a prescription in a full-service pharmacy?
a. \$2.00 b. \$3.35 c. \$6.00 d. \$1.25
4. Out of every ten new drugs marketed, on average, how many achieve sufficient revenue to cover costs and make a profit?
a. 8 b. 2 c. 6 d. 1
5. Considering drug prices and manufacturing wages in the U.S. & Mexico, how long do Mexicans work compared to Americans to pay for Rx drugs?
a. same # hours b. Half as long c. more than twice as long
6. What is the current estimated cost of bringing a new drug to market?
a. \$175 million b. \$359 million c. \$500 million d. \$100 million
7. Which component of health care costs are patients most aware of because they pay out of pocket?
a. physician b. prescription c. hospital d. emergency room
8. What percent of sales, on average, is spent on research by research-intensive pharmaceutical manufacturers?
a. 25 b. 16 c. 8 d. 11
9. Total health care expenditures have risen to almost 13% of GNP since 1960. How have pharmaceutical costs behaved as a % of GNP during that period?
a. risen to 3% b. fallen to 0.5% c. held nearly constant under 1%
10. If pharmaceutical industry profits were eliminated, how much would this reduce total national health care costs?
a. 3% b. 5% c. less than 1% d. 10%

Answers: 1 a. 5%; 2 d. 5-7; 3 c. \$6.00; 4 b. 2; 5 c. more than twice as long; 6 b. \$359 million; 7 b. prescription; 8 b. 16; 9 c. held nearly constant under 1%; 10 c. less than 1%



Critical Thinking & Communication Skills

Another Look at Pharmaceutical Care

Linda A. Wong-Twery, Pharmacy Student, UMAB School of Pharmacy

This article is the seventh in a series written by pharmacy students in the first course of the entry-level Pharm.D. program at the University of Maryland School of Pharmacy. PHAR 516 (Pharmacy Practice and Education) is an introductory course which exposes students to pharmacy practice, pharmaceutical sciences, ethics, communication, and critical thinking. One of the class assignments was to write a critical evaluation on one of three topics: pharmaceutical care, pharmacy technicians, or mail-order pharmacy. This course was developed by MPhA Past President Ilene Zuckerman with the assistance of graduate student Diane McNalley.

Pharmaceutical care, as defined by Hepler and Strand in 1990¹, is the "responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life." The concept of pharmaceutical care evolved as a result of growing economic, sociological and technological changes. While society demands for more accessible and better health care options, an ever widening gap in the federal deficit calls for cost-containment in health care. Furthermore, a general shift in the patients' attitude towards consumerism results in a demand for quality health care and treatment options. Today's patients now ask who they are being cared by and how they are being cared for. As such, pharmaceutical care with its focus on patient outcome and quality of life, if successfully implemented, could conceivably provide an answer to the nation's health care travail.

For the successful implementation of pharmaceutical care as the accepted standard of practice at any one setting, several questions need to be addressed including (1) what type of patients are needing care, (2) what level of care is expected by the patients, (3) what type of training must the pharmacists have, (4) how many pharmacists are needed, (5) how much time to allot to each patient, (6) how to ensure a continuity of patient care, (7) how to relate services to patient care outcomes, (8) how to compensate for the services, (9) what level of responsibility and accountability are pharmacists willing to assume with regards to patient outcome, and (10) what kind of resources are available.

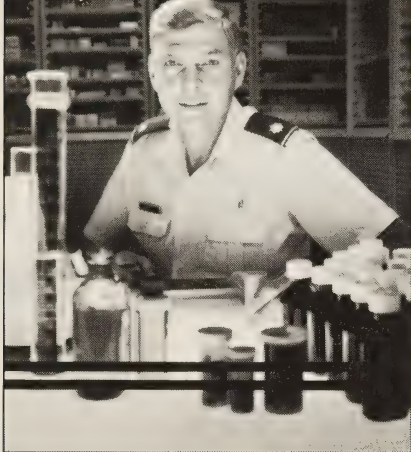
In an ideal environment, pharmaceutical care should be accessible to all types of patients, and focussed on meeting all the needs of the patients through the provision of quality health care. Such a setting requires unlimited manpower and resources. Successful assessment of

Today's patients now ask who they are being cared by and how they are being cared for

patient outcome is dependent on the strength of the patient/pharmacist relationship. To achieve this, members of the staff should have good interpersonal skills. In addition, the patient-pharmacist ratio should be kept as low as possible in order that enough time is spent with each patient for counseling, patient monitoring and the establishment of patient-pharmacist rapport. Furthermore, useful time can be harnessed by providing a good technical and technological support system to help free the pharmacists from duties that could be readily assigned to another or automated.

To allow for greater accessibility to health care for the diverse group of patients, the pharmacists' training should be broad-based and of a generalist's orientation. In addition, members of the staff should be organized into professional practice teams which not only help to foster an environment that promotes professional creativity and initiative, but also provides a support system whereby members are mutually accountable to one another as they strive towards a common goal of achieving definite patient outcome. The level

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of communication fostered between members of staff would also help ensure a continuity of patient care in the event of shifts or different schedules. In addition, teaming up of members from different settings would further help provide for the continuity of patient care as the patient moves from one health care delivery site to another.

In an ideal pharmaceutical care environment, individual pharmacists would operate under a high level of autonomy with the freedom to prescribe or dispense drugs. As such, there should exist an internal regulatory system, consisting preferably of a panel of physicians and pharmacists to function as peer reviews in order that individual pharmacists meet the high standards of practice and that proper drug therapy is being administered. Such a measure would help the pharmacists assume greater responsibility and accountability and develop a discipline for documentation. The latter is also important for securing proper reimbursement for the services rendered.

In addition to providing technical support in the form of incorporating the role of trained pharmacy technicians into practice teams, other support systems such as administrative support and specialist support comprising of staff members who are specialists in different disciplines such as pharmacokinetics, drug information, quality assurance, etc., would be needed to act as resource

pool.

The success of implementing the above model for pharmaceutical care model would depend in part on the attitudinal orientation among pharmacists. The quality of care that a patient receives would in essence depend on how patient-oriented the individual pharmacist is. In reality, social factors such as differences in culture, race or socioeconomic status would pose potential barriers in the establishment of patient-pharmacist rapport. Another factor that could deter the process is the cost of operation, how to adequately fund the support systems or pay the optimal salaries to members of the staff without incurring a sharp increase in the price of drugs or translating pharmaceutical care services into a commodity. In either case, the net effect could be an increase in the health premiums of insurance coverage or a loss in patronage by other health insurance companies. Furthermore, few patients are willing to pay for the extra service (pharmaceutical care) which they, traditionally, were able to obtain free of charge. Consequently, this would lead to the exclusion of certain population of patient (usually those belonging to the lower income bracket) and therefore defeating one of the primary goals of the model pharmaceutical practice, *i.e.*, service and accessibility to all patients.

The model pharmaceutical care practice described

above would also require members to assume greater level of responsibility. In reality, pharmacists may not be at all comfortable with the idea of being made accountable for drug that someone else dispenses. In addition, tradition dictates how pharmacists interact with physicians; pharmacists tend not to want to intervene in a drug therapy process or actively question a physician's drug recommendation for fear of provoking interprofessional confrontation.² As such, success in implementing the above model care practice would be limited unless pharmacists develop a new mind set or philosophy towards patient care and achieve within themselves a new height of self-confidence with regards to their knowledge, professional training and capacity to influence patient outcome from a drug therapy process.

For the present moment, pharmaceutical care and its underlying concept is not well defined; to the public, this form of health service may be viewed as another innovative money-making scheme. Nevertheless, this form of health care practice has already been implemented in a number of hospital settings including the neonatal in a number of hospital settings including the neonatal intensive care unit at the University of Cincinnati Hospital³ and ambulatory care center at Health One Unity Hospital in Minnesota.⁴ In the latter, a significant reduction in the medication costs and an improved quality of care as a result of pharmaceutical care intervention was noted. In light of these findings, the outlook for pharmaceutical care practice within the realm of future health care appear optimistic. In particular, potential application of this practice could be found among the elderly, a segment of the population that is steadily increasing and will comprise nearly 20% of the population by the turn of the century.⁵ These patients are known to exhibit high incidences of drug-related problems,^{5,6} much of which could be averted with adequate counseling on proper drug use and careful patient monitoring. For these group of patients, the demand for an improved quality of life may mean more than the cost of drug. As such, adding value or personal touch to the prescription could potentially go a long way towards improving health care.

R

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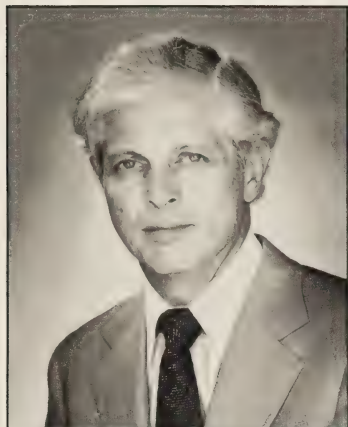
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Academy of Managed Care Pharmacists

A First Timer's Visit to an AMCP Annual Meeting

Jerome Fine, P.D., Associate Professor, University of Maryland School of Pharmacy



The sixth annual convention of the Academy of Managed Care Pharmacists was a vibrant meeting of fourteen hundred people associated with managed care pharmacy. *Impressive* was the general age of the participants, younger than many at other pharmacy conventions. *Noted* was the number of new business entities that hinted of entrepreneurial opportunities. *Significant* was the level of attendance at the sessions -- except the poorly attended presidential banquet.

Even though I have worked in participated in both state and national associations, it was a unique experience.

Keynote speaker, Norman Ornstein, and a lead-off panel moderated by Dr. Tim Johnson, spoke of the forces leading both the medical and pharmaceutical industry into managed care for the population, and its increased challenges to the medical care system. For example, the national health economy had a budget that used to be 30% mandatory and 70% discretionary; it is now 70% mandatory and 30% discretionary, and rapidly rising. Panel members mentioned advances in technology and electronic communication that have changed the entire drug distribution system. The country is approaching, if not already entering a time of "allocation of resources." And this is before any national health care reform.

Managed care speaks to the quality health care of individuals as evidenced by outcomes of therapy and quality of life -- looking to the economic impact of a disease state

and its cost to the community and the health care system. This must be related to the micro-management of an individual's pharmacotherapy and the AWP of the drug product. The conceptual change will be from the cost of the product to the total cost of medicating and monitoring the patient to produce an improved outcome.

A recurring theme in managed care was control. Control in pharmacy distribution systems includes in-house pharmacies, contracted networks, mail service, and on line, real time, claims progressing and, of course, formulary management.

A valuable session for me was "Managed Care Curriculum in Pharmacy Schools ...A Grass Roots Approach". Presenters included: Timothy Covington, Samford University; Richard Gourley and Marvin Shepard, University of Texas; Christopher Rodowskas, Nova Southeastern University; Edward Kelly, III, University of Connecticut; and Warren Salmon, University of Illinois at Chicago.

There was general agreement that managed care should be a practice philosophy, pervasive and woven through the curriculum. Alabama, Tennessee, and Illinois offer post Pharm.D. residencies in managed care. Most of the schools offered rotations or clerkships in managed care, and Alabama offered a didactic two-semester credit hour course in managed care pharmacy.

Tim Covington described a need to educate a three dimensional practitioner. He stated there was

overkill in clinical and pharmacotherapeutic practitioners and, "criminal neglect in the area of human resource management and fiscal management." He stressed that students must be exposed to informational literacy. in twenty-eight points (see attachment).

The two hour didactic elective at Sanford emphasizes drug benefit management from clinical, fiscal, and human resource perspectives. The school offers a four credit, five week, two hundred hour externship, and a post Pharm.D. twelve month residence program in managed care pharmacy that carries a \$24,000 stipend with liberal travel benefits.

When TennCare came to Tennessee the state went from 2% managed care to 20% managed care overnight, and the school lost 20% of its pharmacy externship sites. Gourley said they bring pharmacists from outside the faculty to teach managed care topics. They offer two residencies in managed care pharmacy.

John Salmon of the University of Illinois described a tripartite relationship of the new practice environment, research, and manufacturer support. The school offers an elective in managed care pharmacy with an administrative rotation. Salmon stated there should be some shift in residencies from hospital, clinical, retail, to ambulatory care and administration with the needs of managed care organizations, input into change of drug delivery systems and a need for expanded clinical roles. These changes need the support of the pharmaceutical industry and the profession.

Kelly, of Connecticut, claimed a need for support from the community. The school can't design a program unilaterally. He wants a clear cut proposal for an experiential program. The school is willing to adjust faculty and clerkship rotations. There is a need for more rotation sites.

Dr. Rodowskas addressed how managed care issues must be viewed

Informational Literacy

Some of the topical areas requiring informational literacy and competency by faculty, pharmacy students and pharmacy practitioners include following:

- Accountability in health care.
- Cost effectiveness/cost efficiency in health care.
- A health outcome oriented system of health care delivery.
- Implications of governmental or quasi-governmental regional alliances.
- Implications of access to health care for all Americans (universal coverage).
- Implications of a Medicare outpatient drug benefit.
- Implications of a capitated payment system.
- Implications of portability of health care benefits.
- Implications of expenditure caps.
- Implications of broader application of formularies, the formulary system, prior-authorization and therapeutic substitution processes.
- Implications of the drug use evaluation (DUE) process from both a retrospective and prospective perspective.
- Pharmacists role in pharmacotherapeutic case management.
- Accelerating health care costs.
- Cost containment realities.
- Waste and fraud in health care.
- Lack of positive correlation in many instances between rising cost, quality of care and positive health outcomes (e.g. value for dollars expended).
- Emerging influence of ultimate payers (i.e. government and corporate America).
- Implications of more sophisticated electronic drug benefit management systems.
- Changing demographics of managed care.
- Influence of thought leaders, change agents and decision makers in drug benefit management.
- Emphasis on preventive care/wellness.
- Primary care/gatekeeper emphasis.
- Implications of wider application of the Pharmacy and Therapeutics Committee process in managed care.
- Policy and procedure development and refinement.
- Prudent staffing practices (e.g. recruitment, interview, selection, hire, evaluation, productivity assessment, staff development).
- Legal and regulatory issues.

from the angles of legality, ethics, and strategies for reimbursement.

Managed care needs the schools to develop clinical managers, fiscal managers, and human resource managers. They should have expertise in pharmacoeconomics, interpersonal skills, and communication skills as well as

clinical management ability. Pharmaceutical care should be taught with less emphasis on didactic learning and more applied training. Instead, tomorrow's students who are going to have to practice in some form of managed care environment will need more focused education on developing higher order thinking skills

and problem solving ability. Education needs to change from providing fact after fact to assuring precision in drug therapy management and optimal health outcomes for drug therapy with a minimum of therapeutic misadventures.

An exciting afternoon session entitled "Outcomes Based Community Pharmacy Practice" described an enviable community practice. Four disease states were identified, pharmacists were selected and trained, and the retail store was redesigned to include an office and laboratory. The deal was to improve patient quality of life and provide economic value to the health care system. Patient histories were taken, interventions documented and physicians copied on reports, interventions and progress of patients. Patients were scheduled for appointments for lab monitoring and educational programs. The cost of the disease state management was compared to the average cost of the average cost of previous method of

treatment. The emphases was on managing the patient, not the AWP of the drug.

The attitude of the group was upbeat. The pharmaceutical manufacturers made a strong showing as evidenced by the number of companies represented through program underwriting and sponsorship as well as by the number of representatives from the companies. At the "Colleagues in Conference" sessions, each company had a small booth *sans* exhibit, set up for personal discussion with company representatives.

From my discussions with several of the drug companies it became apparent that manufacturers are looking for "partnerships" with the managed care pharmacists in disease state management. One goal repeatedly stated was integrated medical record information -- a blending of drug product information and disease state information. A need exists to effectively track and monitor progress of patients and compliance with control requirements.

The industry conducts outcomes research in conjunction with obtaining reimbursement for and potential registration of its products. The industry wants to be fully involved in the infrastructure of managed care.

The partnership perceives a revalued paradigm changing the cost of product, volume discount, and market share to risk sharing, capitation, and diseases state management.

The pharmacist's interest in the patient and concern for the patients health rally hasn't changed; however, the approach to the patient's care and the economics of caring for the patient are undergoing a profound change. We must adapt to and prepare for the is metamorphosis.

In conclusion, I encourage every pharmacist to attend a conference, convention or educational seminar of the Academy of Managed Care Pharmacy. I think you will find it very surprising and full of challenges and opportunities for restructuring the way you practice. R

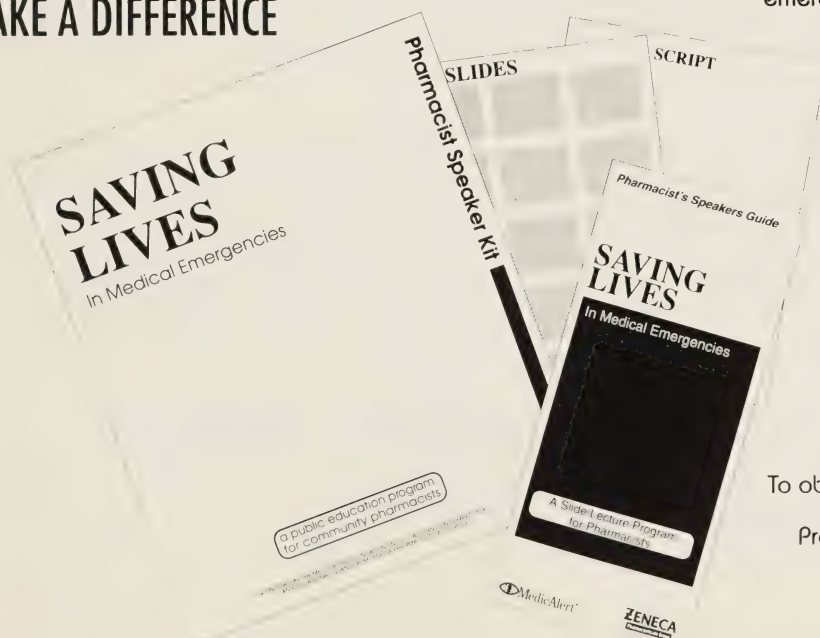
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No. 43

ZERO—MUCH ADO ABOUT NOTHING

A zero means nothing, right? Well, yes. But even nothing when it is missing can play a significant role in medication errors when used inappropriately. The USP Practitioners' Reporting NetworkSM (USP PRNSM) and the Institute for Safe Medication Practices, Inc. have received reports where the nonuse of a zero in the expression of strength has caused potential and actual medication errors.

In one instance, a 0.1 mg prescription of injectable dexamethasone for a newborn was misinterpreted to mean 10 mg. The prescriber wrote an order for dexamethasone ".10 mg IV" but failed to use a leading zero to indicate the presence of a decimal. The pharmacist did not see the decimal in front of the one and prepared what was believed to be the correct 10 mg dose. This error was prevented only by the astute observation of the nurse administering the drug who realized the dosing error and did not give the hundred-fold overdose to the infant.

Another incident* describes the agony a patient suffered after experiencing a severe sunburn subsequent to using a repigmenting agent. The details of the report follow. A dermatologist wrote a prescription for methoxsalen topical solution ".1 %." The pharmacist did not notice the naked decimal and instead dispensed the 1% topical lotion. Two hours after applying the 1% lotion the patient underwent ultraviolet light treatment. The reaction to this ten-fold concentration of the product was extreme and resulted in the patient's hospitalization, further medical complications, and lengthy litigation. If a leading zero (i.e. "0.1%") had been written to indicate the presence of a decimal, it is more likely that the pharmacist would have dispensed the correct strength product.

The importance of using a zero appropriately for responsible product labeling and in professional practice first was included in the *USP XXII-NF XVII* (published in 1990). *Drug Product Quality Review*, No. 28 entitled *An Expression of Strength*, addressed the problems caused by trailing zeros, such as inappropriately expressing the product strength as the whole number "2.0" rather than "2" with no decimal point. The current *Labeling* section in the *USP XXII-NF XVII General Notices* states, "In order to help minimize the possibility of errors in the dispensing and administration of drugs, the quantity of active ingredient when expressed in whole numbers shall be shown without a decimal point that is followed by a terminal zero..." Therefore, any product label for an official product that uses a terminal zero to express a whole number is not compliant with USP requirements.

The problems with leading zeros (naked decimals) cited above are being addressed presently by USP. The November–December 1993 issue of *Pharmacopeial Forum* contained a proposal for inclusion in the *Labeling* section of the *USP General Notices*. That proposal is meant to reduce further medication errors resulting from confusing labels and prescriptions/orders. The proposal, a continuation of the "terminal zeros" statement in reference to product labels, states, "The quantity of active ingredient when expressed as a decimal number smaller than one shall be shown with a zero preceding the decimal point (e.g., express as 0.2 mg [not .2 mg])." *USP 23-NF 18* (published and released on July 1, 1994) includes this proposal. This new requirement is scheduled to go into effect as of January 1, 1995. Manufacturers, labelers, and health care practitioners are encouraged to be aware of this new requirement.

To report problems with drug products or to receive further information, call the USP Practitioners' Reporting NetworkSM at 1-800-4-USP PRN or the USP/ISMP Medication Errors Reporting Program at 1-800-23-ERROR.

*Haserick, J. The Case of the Overlooked Decimal Point. *Medical Economics* April 12, 1993; 97.

Issued 7/94

Litigation Update

The Causation Issue

David B. Brushwood, R.Ph., J.D.



The Supreme Court of Vermont recently reversed a jury verdict in favor of a pharmacist. The facts of the case show that the plaintiff was suffering from pain in her chest and a fever. Her physician diagnosed an infection and he prescribed Eryc. The pharmacist, to whom the patient took the prescription, filled it with Esgic, apparently misreading the handwriting on the prescription. The patient did not notice the mistake.

The patient took two tablets before bed and two more the next morning. Because she felt queasy and "cloudy," she decided to take a shower. She fainted soon after stepping into the shower, and came to with a "stinging sensation" in her back, which she believes was caused by striking the water faucet when she fell. She returned to her physician and was informed that she had received the wrong medication. She went again to the pharmacy where the pharmacists apologized for the mistake and gave her the correct medication. For about three weeks the patient considered the incident a "minor scrape and bruise," but the pain continued and litigation resulted.

At trial, the plaintiff presented expert witnesses who testified to their opinion that the plaintiff's continued lower back pain was due to the fall in the shower, and that the fall was caused by the side effects of the drug Esgic. However, these experts based their testimony, in part, on the plaintiff's medical records, in which other physicians had indicated their belief that the patient's problems did not result from the misfilled prescription.

The medical records were admitted into evidence, and the pharmacist's lawyer referred to them at trial as "silent witnesses." The jury rendered its verdict that the pharmacist had been negligent, but that this negligence had not caused the patient's harm. This verdict was reversed on appeal, because the medical records should not have been considered as significant evidence by the jury. Under such circumstances, medical records can serve as the basis for testimony, but they cannot be considered the equivalent of testimony. The case will proceed against the pharmacist.

As is the case with most misfilling errors, this is one that probably could have been prevented by patient counseling. **R**

Based on: *Keus v. Drug, Inc.*, 1994 Westlaw 419772 (VT August 5, 1994). Copyright 1994, David B. Brushwood. All Rights Reserved. Reprinted From *Dickinson's Pharmacy*, October 1994.

About the Author

David Brushwood is Professor of Pharmacy Health Care Administration at the University of Florida. His articles on cases affecting pharmacies and pharmacy are provided as a courtesy to state pharmacist associations. Questions on legal issues affecting Maryland practice should be directed to your legal representative or the Maryland State Board of Pharmacy.

Continuing Education Quiz

October 1994 -- AIDS Drugs

This month's questions are taken from the article on recently introduced drug therapies for AIDS that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members \$10.00). The completed quiz for this issue must be received by April 30, 1995. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

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1. *Pneumocystis carinii*, the dangerous opportunistic organism that invades AIDS patients, is a:
 - a. bacterium.
 - b. protozoa.
 - c. spirochete.
 - d. virus.
2. The organism referred to in question 1 causes:
 - a. bacteremia.
 - b. hepatitis.
 - c. pneumonia.
 - d. renal shutdown.
3. When the FDA assigns the code "1P" to a new drug application, it signifies that:
 - a. there is a prior drug just like it already on the market.
 - b. the drug is available in a parenteral dosage form.
 - c. the agency will give priority consideration to the application.
 - d. pretesting will be necessary before the drug is eligible for approval.
4. When compared to Mepron, sulfamethoxazole-trimethoprim:
 - a. has a higher failure rate due to adverse effects.
 - b. has a higher mortality rate during 3 week treatment courses.
 - c. has a higher failure rate due to lack of response.
 - d. is more effective.
5. Mycobutin is pharmacologically most similar to:
 - a. Rifampin.
 - b. Zovirax.
 - c. Mycostatin.
 - d. Retrovir.
6. Patients receiving mycobutin should be advised:
 - a. to avoid excessive exposure to sunlight.
 - b. to be careful driving or operating hazardous equipment.
 - c. the drug discolors urine, saliva, tears and sweat to a brown to red-orange color.
 - d. to take the dose four times a day at evenly spaced intervals.
7. Trimetrexate must be administered with:
 - a. antacids.
 - b. leucovorin.
 - c. normal saline.
 - d. vitamin C.
8. Hivid, Videx and Retrovir all inhibit the enzyme:
 - a. DNA polymerase.
 - b. formadyl transferase.
 - c. monoamine oxidase.
 - d. reverse transcriptase.
9. The toxicity of greatest concern with the use of Hivid is:
 - a. acute pancreatitis.
 - b. gastric/duodenal ulceration.
 - c. intermittent claudication.
 - d. peripheral neuropathy.
10. Of the drugs reviewed in this lesson, the product for which it is most important to take each dose with food is:
 - a. Hivid
 - b. Mepron
 - c. NeuTrexin
 - d. Rifabutin

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NO. 11



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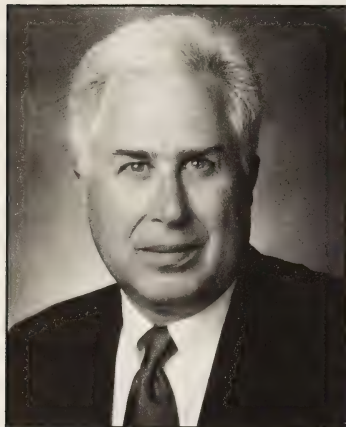
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President's Commentary

Arnold Davidov, P.D., 1994-1995 MPhA President



On Tuesday, November 8, 1994, I and MPhA Executive Director David Miller, along with state executives and pharmacy association presidents from the Mid-Atlantic Region met with nine upper-level representatives of Merck, Medco, and Paid. This invitational meeting requested by Merck lasted from 9:00 am to 3:00 pm.

To be honest, when I first received the invitation, my initial thought was to decline. I, like most of you, thought that the purchase of a mail-order company by the world's largest pharmaceutical manufacturer was a direct slap in the face of community based pharmacy practice. Here, after years of being their primary source of product distribution, was Merck positioning itself in such a way as to steal away my business and give it to a faceless mail-order company. Where will I be with Merck as a manufacturer, distributor, claims processor, and pharmacy?

Personal reactions aside, I realized that I had a duty to you, the MPhA member, to at least hear there side of the story and to determine what impact this and subsequent mergers will have on our profession and our Association.

Frankly, I'm glad I went. The general focus of the meeting was to explore the pharmacy issues that face us and to identify common ground upon which we can grow our business and benefit the pharmacy profession. We were able to express (politely and not so politely) the anger, apprehension, and fear that surround the entire merger and the actions of Medco and PAID. Their representatives answered our questions frankly when they could and got a better understanding for the concerns of pharmacists and our associations.

What did I learn that I think you should know?

First, even with the growth of managed care, HMO's, and other non-traditional distribution systems, Merck still sells more than 80 percent of its product line through independent and chain community pharmacies. They recognized that they can ill afford to alienate their major customers. Second, while you and I think of Medco as a mail-order company in direct competition for our patients, less than ten percent of Medco's business is its National Rx mail-order system. The lion's share of business is generated through the Medco pharmacy benefit management services it provides to large and small employers. In other words, Medco is more a PBM like PCS, Paradigm, and Express Scripts than it is mail-order. Third, Merck's purchase of Medco was the ability to obtain the maximum amount of lives managed/covered by a PBM so as to preserve their market share and access to formularies. And who was the biggest PBM around? Medco.

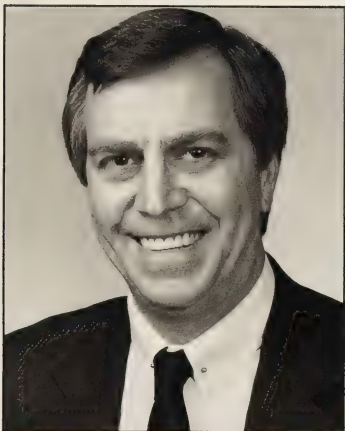
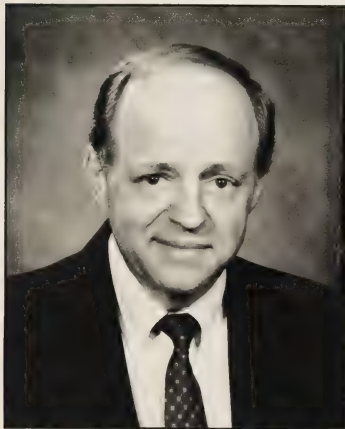
Much has been written and said about Merck's acquisition of Medco/PAID. I'm sure that much more is to come. And although I now have a better understanding of Merck's decision to purchase Medco and a greater appreciation for what they are trying to do as a corporation, I will be withholding my final judgement until a track-record of the company's performance consistency with the company's words has been established. **R**

OTC Dandruff and Seborrhea Products

Overview of Conditions and Patient Counseling

Thomas A. Gossel, R.Ph., Ph.D., Dean, Ohio Northern University

J. Richard Wuest, Pharm.D., Professor of Pharmacy Practice, University of Cincinnati



This educational program is made possible through a grant-in-aid from

SEARLE

Dandruff and seborrheic dermatitis (seborrhea) are afflictions for which pharmacists are called upon to suggest treatment. While the two disorders have pathologically different etiologies, it is not always easy to distinguish between them. Unless the conditions are severe, both can be managed effectively with the same OTC products.

Anatomical/Physiological Considerations

The skin's cells are formed continually in the basal (lower) level of the epidermis. They divide by mitosis to form daughter cells which then migrate upward toward the skin's surface. As they approach the surface, they die and become dehydrated because the upper layers of the epidermis are not supplied with a nutrition source. The skin's vascular supply is limited to the dermis. These highly compacted (dry) cells are known collectively as the keratin layer, and as a result of normal shedding forces on the skin, with replacement from cells slough off. This process is continuous and, since the cells are normally shed individually, shedding is usually imperceptible.

In dandruff and seborrheic conditions, however, the shedding rate of these cells is excessive. When they come off in large clumps, these conditions are perceivable as dandruff and seborrhea.

Dandruff

Dandruff is defined as a chronic, noninflammatory condition of excessive shedding of epidermal cells that come off in large clumps or scales. Dandruff scales appear dry, white or grayish. They are most commonly seen in small, round patches, especially on the crown of the head. However, when the condition is severe, these patches may cover the entire scalp. Dandruff itself causes occasional itching, but this is the exception. Generally, itching may indicate the presence of some other dermatitis related condition.

Other theories associated dandruff with improper diet, hormone imbalance, or vitamin B complex deficiency. None of these have been proven, however.

One hypothesis that still has some proponents, even though it has been shown not to be significant, is that dandruff is caused by a yeast-like fungus. The presence of *Pityrosporum ovale* was first observed years ago on the scalp of victims of dandruff. However, today it is generally agreed by most experts that *P. ovale* can be found on the scalp of all persons. Others microorganisms have also been proposed as possible causes of dandruff. At present, it is impossible to determine definite conclusions on any of them. One particularly interesting note is that the organism *Propionibacterium acnes* is frequently decreased significantly on scalps of individuals who have dandruff. This microbe is associated with acne.

The most visible symptom of dandruff is scaling of large clumps of cells called squamae. This flaking is seasonal being most severe from October through December, and least common during the summer months. These associations probably reflect seasonal humidity conditions (i.e., low humidity: dandruff present; high humidity: little dandruff problem). Dandruff is also subject to several other features (Table 1), all of which can be used to differentiate the condition from seborrhea.

Dandruff generally begins with the onset of puberty and peaks in intensity in the early twenties. It declines in middle and old age. Estimates suggest that as many as 70 percent of all Americans have been afflicted with it at some time.

Members of both sexes are affected equally. While sometimes described as a trivial condition, it is only trivial to the person who does not suffer from it. The large number of proprietary products available for treating dandruff attests to this.

Seborrheic Dermatitis

With seborrhea, the rate of turnover of epithelial cells is even greater than in dandruff. Dandruff is localized almost entirely to the scalp. Seborrhea is also encountered mostly on the scalp (seborrhea capitis), but it may also occur on other hairy areas of the body and in the skin-fold regions. Sites of occurrence are listed in Table 2. These areas contain the highest concentration of sebaceous glands, as well as the largest concentration of skin bacteria and yeasts.

Causes. As with dandruff, numerous theories have been advanced over the years concerning the pathogenesis of seborrhea. Likewise, the precise cause is not known.

One theory states that excessive secretion of sebum induces seborrhea by providing a rich oily substrate for bacteria and fungi to metabolize into irritating substances (e.g., free fatty acids). Even though the name seborrhea defines excessive sebum flow, it

Important Characteristics of Dandruff and Seborrhea

Characteristic	Dandruff	Seborrhea
Site	Scalp	see Table 2
Borders	Indistinct	Indistinct
Inflammation (redness)	No	Yes
Appearance of scales	Dry, grayish-white	Greasy
Age at onset	Puberty	Puberty
Itching	Variable	Usual
External factors that worsen condition	Cold weather	Stress, poor health
Rate of epidermal turnover	Twice normal rate	More than twice normal rate
Duration	Can persist for life, diminishing in middle and old age.	Can persist for life, frequent exacerbations and remissions.

Table 1

as not been shown that all persons with the condition have increased sebum production. In fact, in carefully controlled tests, patients with the disorder often do not have increased sebum production when matched when matched to their age-related counterparts.

The condition has also been linked to fungi and bacteria. For example, *Candida* organisms are present in significantly higher numbers in infants with cradle cap. *P. ovale* and *Staphylococcus aureus* are found in higher are found in higher than normal concentrations in patients with seborrhea. The concentration of *P. acnes* is more depressed in persons with seborrhea, than in those with dandruff.

Other suggestions as to etiology suggest that seborrhea may be due to food allergies, vitamin B complex deficiency, an autoimmune deficiency, or to changes in weather. None of these has been proven, however.

Cradle Cap

This condition may represent an infantile form of seborrhea. It involves the scalp, skin behind the ears, nasolabial fold, neck, armpits, umbilicus, and diaper area. The prevalent age for cradle cap on the scalp is

within the first couple of weeks of life. It results from accumulation of keratin and dirt. The likely reason for its occurrence is that mothers are hesitant to wash the area, fearing that if too much pressure is applied to the "soft spots" on the baby's head, permanent brain injury will result. This is, of course, an unfounded fear.

The condition normally clears within a month and generally does not recur. Rarely, it may evolve into dermatitis with itching, and spread to the cheeks forehead and extremities. Except for these severe cases, cradle cap can be controlled by careful and thorough washing with soap and water. There are no longer any OTC products labeled specifically for use on cradle cap.

Symptoms and Occurrence

Although the two conditions differ considerably, symptoms of seborrhea resemble dandruff in several important ways. Seborrhea produces dull, yellowish-red lesions. They are localized on one area of the scalp or hairy surface, but the condition may be more diffuse with large areas being affected. Unlike dandruff, itching is common with seborrhea.

Seborrhea fluctuates in severity.

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Whereas dandruff occurs at a relatively stable intensity, seborrhea can be severe one time, quite mild the next occurrence. Seborrhea appears during times of stress. It is characterized by inflammation and crusting, and may involve the eyebrows and eyelashes and cause blepharitis (inflammation of the eyelids).

The condition is seen most commonly in middle-aged individuals and the elderly. Women are affected more frequently than men. It rarely occurs in children. About 12 million Americans are reported to suffer from seborrheic dermatitis.

General Treatment Information

There are no definitive cures for either condition. Regular use of OTC remedies can control symptoms. Many individuals rely on the principle that if the large clumps or flakes can be reduced in size, their visibility decreases, and hence, the dandruff condition will be "controlled." Regular washing of the hair and scalp helps a great deal. This can be done daily, although once every second or third day is usually sufficient, except in severe cases.

The classification of OTC agents is presented in Table 3. Categorizing the agents is difficult because two or more effects may be attributed to the same ingredient.

Treatment of Dandruff

Antiseptics (antimicrobials). Because of the theory that microorganisms are a possible cause of dandruff, antiseptics have been employed to treat this condition. These include benzalkonium chloride, iodoquinol and povidone iodine. Their inclusion in OTC dandruff remedies is of questionable value since the microbial induced dandruff theory is not proven, and secondary infection from dandruff is rarely encountered.

Keratolytics. These agents cause a peeling away of the keratin layer, thus removing the scales. Most likely, keratolytics work by dissolving the

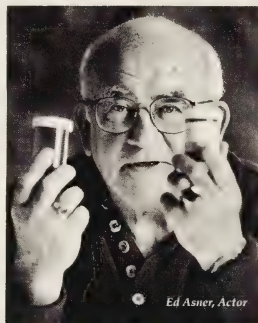
cement substance that holds the cells together, rather than by dissolving keratin. As the scales are loosened, they can be washed away easily. Keratolytics do not prevent scales from forming.

Cytostatics. Use of cytostatics (e.g., selenium sulfide, zinc pyrithione) is a direct means to control dandruff. They decrease the rate of cell growth. Thus, scaling is reduced because there are fewer cells formed per unit of time. These agents lower epithelial cell turnover significantly,

not only those on the scalp, but also of cells elsewhere that come into contact with the medication.

Antipruritics and Corticosteroids. Since sensations of pain and itching are transmitted by the same nerve fibers, local anesthetics have been included in some dandruff products in the past. Hydrocortisone is also antipruritic, so its use in dandruff control could be rationalized. However, dandruff is not an inflammatory condition. While hydrocortisone has been ruled to be safe and

Attention: Pharmacists



Ed Asner, Actor

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effective for the treatment of seborrhea, it cannot be indicated for dandruff. As was mentioned before, itching is not a major complaint with dandruff.

Tar Preparations. While the mechanism of their action is unknown, tar preparations probably act either as cytostatics or keratolytics.

Usual Sites of Seborrhea

Armpits
Back between shoulder blades
Behind the ears
External ear canal
Eyebrows and eyelashes
Mid-chest
Nasal folds
Pubic area and groin
Scalp

Table 2

Treatment of Seborrhea

As stated earlier, misdiagnosis of seborrhea of the scalp as dandruff is not a serious problem. Both conditions are treated basically the same way. In fact, many products are labeled with both indications. Mild seborrheic conditions can be treated with OTC products. If the seborrheic condition involves the ear canal, its treatment is best supervised by a physician.

Coal tar. In strengths of 0.5 to 5 percent, coal tar is safe and effective for both dandruff and seborrhea of the scalp. Patients should be reminded that coal tar can stain clothing, skin and hair (especially gray, blond or bleached). Also, it imparts a strong odor that is objectionable to some people.

Coal tar can cause photosensitivity reactions in susceptible persons. Therefore, patients should avoid excessive sun or ultraviolet light exposure for at least 24 hours after applying the product.

Salicylic Acid. In strengths of 1.8 to 3 percent, salicylic acid is an effective keratolytic for treating

dandruff and seborrhea.

Sulfur. In a concentration of 2 to 5 percent, sulfur is safe and effective for treating dandruff. Though not approved for OTC sale for self-treatment of seborrhea, sulfur continues to be recommended by medical authorities. A concentration of 3 to 5 percent, combined with salicylic acid, can be applied to the scalp or other sites on the body.

Selenium Sulfide. For years, a 1 percent concentration of selenium sulfide has been considered to be effective for controlling both dandruff and seborrhea.

Discoloration of the hair has been noted following use of selenium sulfide. However, this isn't a common occurrence. Patients with dyed hair should first test a small area with the shampoo to be certain no staining will occur. The shampoo should also be rinsed off thoroughly after use. FDA requires manufacturers of selenium sulfide products to state the following warning on product labels: "Do not use if you have open sores on your scalp."

In January 1994, FDA approved the addition of selenium sulfide, micronized -- a finely ground formulation that has a smaller particle size than the previously available form -- to the list of safe and effective agents, in a 0.6 percent concentration.

Zinc Pyrithione. This is safe and effective for controlling dandruff and seborrhea. Concentrations that are approved for marketing as formulation to be applied and then washed off after brief exposure are 0.95 to 2 percent. Formulations to be applied

and left on the skin or scalp must be in the 0.1 to 0.25 percent range.

Advising Patients

In addition to information discussed thus far, a few other points should be passed on to patients purchasing dandruff or seborrhea remedies.

The hair and scalp can be washed with a regular shampoo prior to using the medicated product to enhance the latter's effectiveness. This helps remove dirt and flakes, and allows for enhanced penetration of the medicated product into the scalp. Another shampooing with a non-medicated product may be considered following removal of the remedy. This can eliminate the objectionable odors and discoloring that some dandruff and seborrhea products impart to the hair and scalp.

Selenium sulfide may impart oiliness to the scalp and thus worsen the seborrhea. Its use for this condition should be limited to once every second or third day. If the scalp is especially oily, a product containing salicylic acid and/or sulfur may be more beneficial.

With any OTC dandruff or seborrhea product, patients should avoid contact with the eyes or mucous membranes. If contact occurs, the area should be flushed thoroughly with water.

OTC products for dandruff and seborrhea work well for most people. However, if a product fails to provide relief, another one that has different ingredients and mechanism of action

Dandruff/Seborrhea Remedies Safe and Effective for OTC Use

	Dandruff	Seborrhea
Coal tar derivatives (shampoos)	XXX	XXX
Salicylic acid	XXX	XXX
Selenium sulfide	XXX	XXX
Sulfur	XXX	
Zinc pyrithione	XXX	XXX
Salicylic acid/sulfur combos	XXX	

Table 3

could be tried. If such products still do not correct the problem, the individual should contact a physician. The person may have a disease more serious than simple dandruff or seborrhea.

OTC products for dandruff and seborrhea should not be used on children under two years of age, unless under the supervision of a physician. This precaution is warranted because their skin surface in proportion to body weight is greater than that of adults. Furthermore, children do not have a fully developed hepatic microsomal enzyme system, so they cannot metabolize potentially toxic substances that are absorbed as well as adults can.

To avoid possible damage to the eye, seborrheic conditions that involve the eyelids should only be treated by a physician and not be self-medicated.

FDA requires the following instructions for these products, and they should be reinforced by the pharmacist:

- For all products to be applied and washed off (e.g., shampoos and pre/post shampoo rinses): "For best results, use at least twice a week or as directed by a doctor."
- For all products to be applied and left on the skin or scalp (e.g., creams, ointments, lotions, hair-grooms): "Apply to affected areas once to four times daily or as directed by a doctor."

Patients should be instructed to seek professional assistance if their condition does not improve within several weeks of using a medicated shampoo. This advice is also valid if the condition appears on other areas of the body.



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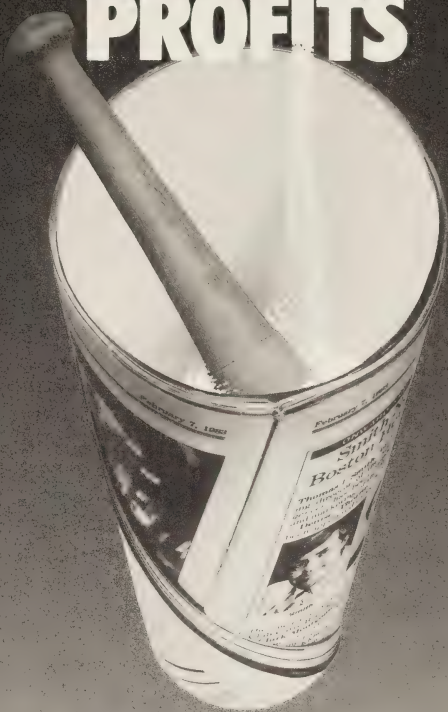
Ways to Handle Patient Complaints

Here are some guidelines for dealing successfully with customer and patient complaints:

- R Take the complaint seriously. It may seem trivial to you, but it's important enough to the patient to justify the time involved in writing a letter, calling or coming to the counter.
- R Listen. Hear the person out before you say anything.
- R Restate the problem. Ask questions until you are able to see the situation from the customer's point of view.
- R Find out what the customer wants. A refund? A discount? A replacement?
- R Maintain objectivity. Your job is not to point the finger of blame but to investigate the facts and find a solution.
- R Empathize. Statements such as "I can understand why this situation has upset you," will convey concern and reassure the patient that you are not taking the complaint lightly.
- R Resolve the problem -- or explain why company policy prevents you from doing so. Tell the patient exactly what you're going to do and when he or she can expect a resolution of the matter.
- R Follow through. If you tell the patient you'll call Friday, do so.
- R Thank the patient for complaining. When customers don't complain, you can lose their business and confidence without even knowing.

Source: BBP Customer Service Management Bureau of Business Practice.

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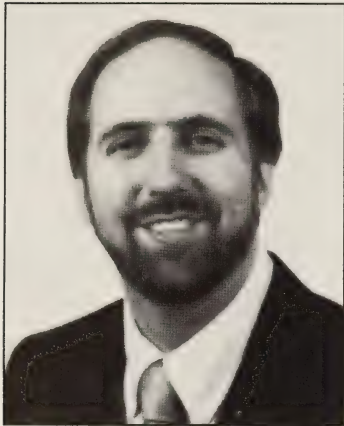


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Landing Your Ideal Pharmacy Job

Part I -- Identifying Your Options

Glenn Lichtman, P.D., PharmaSTAT



Looking for a new job? You are not alone! Like you, many pharmacists are now seeking new employment. Jobs are not as easy to find as they used to be. Remember when you were in pharmacy school? Everyone told you there were plenty of jobs in pharmacy. All you had to do was to graduate and the pharmacy employers would beat a path to your door. At least that's what happened at the school job fairs. All those representatives with warm smiles, offering you what you thought at the time was all the money in the world. Not only would you be able to pay off those student loans, but you could also buy a new car, go out to dinner, and give up that pizza delivery job forever!

Then you were hired, and reality quickly set in. No more smiling faces from the higher ups in your company's administrative office. When you see your recruiter on the street, he has no idea who you are. All the promises of flexible scheduling, regular pay increases, and chances of advancement have long since disappeared. *You're ready to move on!*

1. Determine if you are headed in the right direction. If you are a hospital pharmacist, do you want to try retail, home health care, or long term care pharmacy? If you are not happy in your specific area of practice, changing employers without changing your practice may not be the answer. Many unhappy pharmacists are just in the wrong setting for their particular personality. I have seen very quiet, shy pharmacists in busy retail pharmacies. These individuals tend to be overwhelmed by too much patient contact. An

outgoing, boisterous personality may be bored checking unit dose cassettes all day. A change of settings would benefit both of these pharmacists.

Finding Job Openings

Here are some advantages and disadvantages to several common methods for finding a new job.

The "word of mouth" method.

Perhaps a colleague knows of an opening at his/her place of employment. You may be able to fill an opening before it is advertised. If your friend had a good relationship with the person in charge of hiring, and puts in a good word for you, you may have an advantage over other candidates for this job.



If you are concerned about your employer finding out that you are seeking new employment, this method can be very dangerous. Pharmacy is a very close profession. If your boss knows you are looking for a new job, he/she may replace you before you have found new employment. This method is also the most limited, and if this is the only method you use, you will only hear about a small portion of all the jobs available.

The newspaper ad. When scanning newspaper ads, you can be anonymous. Nobody but you will know you are seeking new employment until you call to inquire about the job. All phases of pharmacy are represented in newspaper help wanted ads.

This method of seeking new employment could also be dangerous if you are concerned about your current employer discovering your job search. When you respond to these ads, you usually do not initially speak to the person responsible for hiring. This means several people are given your name before it reaches the appropriate individual. The more people who know you are unhappy with your current employment, the more likely it is your current employer will know you are seeking new employment.



as advantages over "word of mouth" and your local newspaper.

Trade journals.

Employment newsletters are growing in number every year. Some concentrate on one geographical area, others are nation wide. If you are looking to move to a different area of the country, this method

To see how limited these publications are, count the number of jobs for your state. They rarely list more than two or three jobs per state, and many times these jobs are filled by the time you receive the publication. You also have the same problems of confidentiality with this method as you do with newspapers and "word of mouth."

Agencies. A good pharmacist's agency is "plugged into" all of the above methods, but also has one major advantage. *An agency will receive job orders from clients that do not advertise their jobs.* Why would an employer not advertise a job? Well, employers have the same confidentiality issues employees do. Directors, managers, and owners of pharmacies do not want to let their current pharmacist know they will be replaced, for fear of the employee pharmacist leaving before a replacement can be found. When an employer has an agency conduct their search for them, the employer can remain anonymous until the proper pharmacist is found. The agency will also per-screen and pre-qualify applicants specifically for each job, so the number of interviews you will need are minimized. You will deal directly with the agency, and the agency will deal directly with the person responsible for hiring. This will also help protect your confidentiality. If you select the wrong agency, you could be missing opportunities and wasting your time. It is important to select the right employment agency.

The agency you choose should:

- **Be a local company.** Nobody knows your job market like a company that does business there every day. Out of town companies do not have the depth of contacts that a local company can offer.
- **Stay within your field.** A nursing agency knows nurses. An accounting agency knows accounting. Doesn't it make sense to use a pharmacist's agency that knows pharmacists and pharmacy?
- **Have a proven track record.** Yes, every company has to start somewhere. But why let an inexperienced firm learn from mistakes made on you? **R**

Coming next month - the interview, the follow up, the offer, and the acceptance of the job.

About the Author

Glenn Lichtman is the owner of the Mid-Atlantic's largest pharmacy agency, PharmaSTAT. He is also a member of the Maryland Pharmacist Association. The information from this article is drawn from Lichtman's experience of recruiting, placing and employing hundreds of pharmacists during the last eight years.

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Recognizing Pharmacy Excellence

A Call for Award Nominations

Each year, the Maryland Pharmacists Association recognizes professional excellence through a series of awards. To nominate a pharmacist for one of the awards described below, complete the official Award Nomination Form on the back of this page. The Award Nomination Form information should be clear and legible. Forms should be sent to: **Award Nominations**, c/o Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572.

All nominations will be considered by the Past Presidents Council. The Council is responsible for selecting the recipients and their decision is final. Award recipients will be notified in advance of the award's presentation. For consideration, all nominations **must** be received no later than February 15, 1995. **R**

Seidman Distinguished Achievement Award

About the Award Created to honor the major impact on Maryland pharmacy by Henry Seidman, this award is presented for outstanding service by a Maryland pharmacist to the pharmacy profession during *either* the past year or over a period of years. The recipient receives a plaque and clock.

Who is Eligible: Any MPhA pharmacist member who meets the criteria of the award.

1994 Award Recipient: Ronald Sanford, P.D., Catonsville.

MPhA Honorary President

About the Award An honorary position on the Board of Trustees given to a person who has worked for the MPhA or Maryland pharmacy over a long period of time. The recipient receives a plaque and is an official, ex-officio member of the Board for one year.

Who is Eligible Any long standing contributor to the profession or the Association. The honoree need not be a pharmacist or a member of MPhA.

1994 Award Recipient Ralph Small, P.D., Baltimore.

Wyeth-Ayerst Bowl of Hygeia Award

About the Award The Bowl of Hygeia recognizes a pharmacist who has performed outstanding services to the community in any area, with a particular emphasis on non-pharmacy contributions. The recipient receives a plaque, a lapel pin, and a trip to meet with other Bowl of Hygeia recipients.

Who is Eligible Any Maryland pharmacist who has not already received the Bowl of Hygeia.

1994 Award Recipient Ernest Gregg, P.D., Oakland.

Marion Merrell Dow Distinguished Young Pharmacist Award

About the Award Awarded to a pharmacist who has graduated within the past nine years and has made a significant contribution to the profession through service in a local, state, or national pharmacy organization. The recipient receives a plaque.

Who is Eligible Any MPhA pharmacist member who graduated from pharmacy school in 1985 or after.

1994 Award Recipient David Miller, P.D., Monkton.

Dupont Innovative Practice Award

About the Award Established in 1993, this award aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. This may include adding a new service, restructuring a pharmacy and its current services, or developing a completely new practice. The award recipient receives a plaque, a medal, and a framed water-color sketch.

Who is Eligible Any MPhA pharmacist member who meets the criteria of the award.

1994 Award Recipient Phillip P. Weiner, P.D., Baltimore.

Maryland Pharmacists Association

Award Nomination Form

To nominate a Maryland pharmacist for one of MPhA's annual "Recognizing Pharmacy Excellence" awards, this form must be completed in its entirety and returned to the Maryland Pharmacists Association no later than February 15, 1995. All nominations will be held in strictest confidence by the MPhA Past Presidents Council which is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the award's presentation.

Please consider the following nominee for: (*check one*)

- | | |
|--|--|
| <input type="checkbox"/> Seidman Distinguished Achievement Award | <input type="checkbox"/> Wyeth-Ayerst Bowl of Hygeia |
| <input type="checkbox"/> Distinguished Young Pharmacist Award | <input type="checkbox"/> MPhA Honorary President |
| <input type="checkbox"/> Dupont Innovative Practice Award | |

Nominee _____

Home Address _____

Home City/State/ZIPcode _____

Current Place of Employment/Practice _____

Home Telephone Number _____ Work Telephone _____

Name of Nominator _____

Nominator's Telephone Number _____

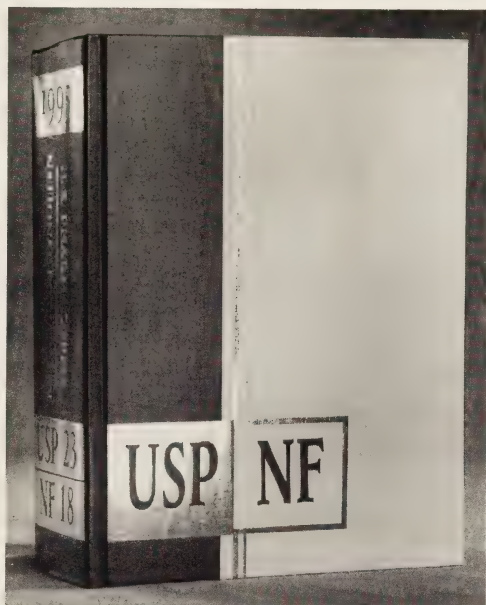
Attach a current resumé or curriculum vitae for the nominee that shows their professional and personal achievements. This information is essential for the Past Presidents Council to make its decisions on which candidates will become recipients of the "Recognizing Pharmacy Excellence" awards. In addition, the nominator should attach a brief letter explaining why the nominee is worthy of receiving this award.

Return the completed form to:
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Litigation Update

Death From Misfilling Not an "Accidental Death"

David B. Brushwood, R.Ph., J.D.



The Court of Appeals of the United States for the 6th Circuit recently upheld a ruling against a woman who was seeking benefits under an accidental death policy after her husband died due to a pharmacist's error.

The material facts in the case showed that the husband was insured by the defendant pursuant to the employee benefits policy purchased through his union. His doctor prescribed Lanoxin, which was filled by an independent pharmacy. The pharmacist mistakenly dispensed Tenormin, and the husband died as a result of ingesting the wrong medicine.

After successfully pursuing a wrongful death action against the pharmacist and the pharmacy, the plaintiff filed an insurance claim for accidental death benefits. The claim was denied based on an exclusionary clause in the insurance policy which said, "No benefits will be paid if loss directly or indirectly results from bodily or mental infirmity, disease of any kind, or medical or surgical treatment for any such infirmity or disease."

The plaintiff claimed, however, that the pharmacist's negligent act did not result from the husband's medical treatment, but instead was merely fortuitously connected to it.

The court noted that an accident could be truly coincidental to medical treatment though proximate in time. The court cited the example that the ceiling might cave in while one is undergoing surgery. This is an accident at the time of medical treatment that is not the result of medical treatment. But in the case at hand, the pharmacist's role was to implement the medical treatment the husband received in the form of a prescription.

Every act of malpractice is to some extent an accident, if one equates "accident" with "unintended." But the court held that the exclusion in the policy focused exclusively on the relationship aspect of the injury rather than its volitional component. Therefore, the husband's death was not an accident, even though it was unintended. The ruling in favor of the insurance company was upheld.

R

Based on: Swisher-Sherman v. Provident Life & Accident Insurance Co., 1994 U.S.App Lexis 28768 (Oct 13, 1994). Copyright 1994, David B. Brushwood. All Rights Reserved. Reprinted From *Dickinson's Pharmacy*, November, 1994.

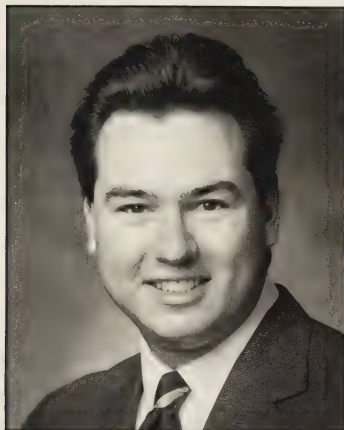
About the Author

David Brushwood is Professor of Pharmacy Health Care Administration at the University of Florida. His articles on cases affecting pharmacies and pharmacy are provided as a courtesy to state pharmacist associations. Questions on legal issues affecting Maryland practice should be directed to your legal representative or the Maryland State Board of Pharmacy.

Surviving a Third-Party Audit

A Guide for Every Pharmacist

David G. Miller, P.D., Executive Director, MPhA



The day can't possibly get any worse. Your partner is leaving tomorrow on a three week vacation. The delivery driver just called to say he had been in an accident. The order from the wholesaler, the one with the vaccines you *promised* to the doctors next door by noon, hasn't arrived and it's already 12:30. Meanwhile, your computer is telling you that Mrs. Allan's prescription is no longer reimbursable even though you filled it for her only two weeks ago.

While juggling the phone with one hand, you open an envelope from Mega-HMO. Finally, you think, here's the check they've been promising for weeks. Think again. It's a letter informing you that Mega-HMO's auditors will be coming to your pharmacy next Wednesday to review your prescription files for compliance with their contract.

In a daze, you pick up on the other phone line. "Hello, this is Carol from BDS Prescription Plan," says a no-nonsense voice. "Representatives from our Review Department will be in your area two weeks from now. They will be arriving at your pharmacy for a complete audit of BDS prescriptions on Monday morning at 9:00 am.

Sound familiar?

First Things First

The first thing to do after receiving notice about a third-party audit is to calm down! Most pharmacists feel a moment of panic whenever an audit is requested. You begin imagining problems... have you forgotten some-

thing? what are they looking for? what have I done wrong?

Actually, you probably haven't done anything wrong. Just as you are obligated to allow audits of your pharmacy's records by third-parties, those same third-parties may be required by *their* contracts with clients to audit a certain number of pharmacies each year. There may be a number of reasons for why your pharmacy was selected. Your pharmacy may do a high volume of prescriptions with a specific third-party -- especially if you are located near a large employer, a clinic or a medical center. You may have several patients using that third-party who have multiple, high-cost prescriptions. Or, more commonly, your practice was just picked at random.

So, what do you do now?

If you are notified by telephone that you are about to be audited, get the name, telephone, and FAX number of the person before proceeding with any more conversation. Inform them that you will need to check your schedule to determine if the time they have selected is appropriate for your pharmacy and your schedule. An audit is a serious process and one that shouldn't be handled or scheduled as if it were a call-in refill. Don't be pressured into confirming a date and time until you are satisfied that it meets with your schedule. If necessary, tell the caller that you will contact them shortly to confirm the date and time, check your schedule, and then call them back.

If you are notified in writing, again make sure that you have the name, telephone, and FAX number of the person in charge of coordinating the audit. This usually appears within the notice or on the company's letterhead.

Read the Contract

Next, get out the most recent copy of your contract with the third-party. If you don't have one, get one. Call the third-party and ask that a copy be sent to you immediately.

Now would be a good time to check to see that you have copies of all your third-party contracts on file in the pharmacy. Pharmacists, unfortunately, tend to be somewhat cavalier about keeping third-party contracts. Remember that they are legal documents to which you have obligated your pharmacy, and possibly yourself, and should be treated the same way you would treat your lease agreement or mortgage papers.

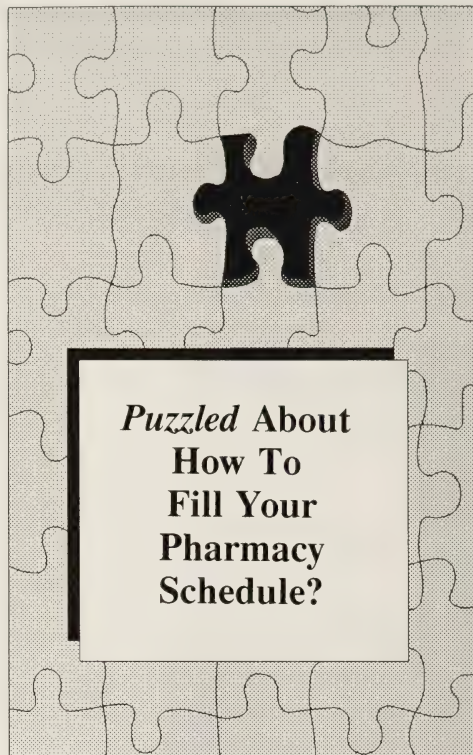
Read the contract. All the way through. Does the contract permit audits? (They almost always do) Does the contract say anything about what the things auditors will be looking for? Are you completely familiar with the requirements of the contract? You may also need to review the third-party's policy and procedures manual, if any was provided, as often this manual is referred to and made part of the actual contract.

Scheduling the Audit

Most third-party contracts with audit clauses include phrases such as "regular business hours" and "reasonable." This means that while the third-party has a right to audit, you have the right to have the audit conducted in such a manner as to not significantly intrude on your transaction of business and patient care. For example, if Monday morning is a hectic time for an audit and Tuesday afternoon is better, you have the right to request that the audit schedule be changed. Also, and this is especially important for small practices, if you will need to schedule additional personnel to be on hand during the audit, you have the right to ask for a schedule change.

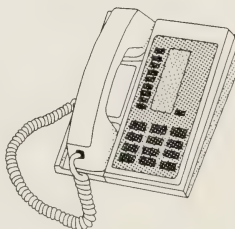
When you call the third-party to confirm the audit, make sure you obtain the following information:

- › Day and date of the audit.
- › Start and end time of the audit.
- › The name(s), company if different from the third-party, address, telephone and FAX phone numbers of the auditor(s).
- › Written confirmation from the third-party to be sent to your pharmacy via FAX or mail immediately.



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Asking About Records

Your next step is to contact the actual auditor(s) if they are different from the person who scheduled the audit. Confirm the date and time of the audit with them, especially if you have changed the originally proposed schedule and if you have been working with another contact person within the third-party.

So far so good; but, this next part is more difficult. Ask the auditors to provide you with a list of prescription numbers that they will want to research? Why?

First, though the third-party has the right to review all documentation including the patient's profile, the original prescriptions, and the signature log for any claim that you submitted to the third-party, they do not have the right to see any prescription or profile information from any other patient. For example, PCS may not review or peruse the prescription records for Blue Cross patients nor may they review the records for your cash paying customers.

You, as the pharmacist, have the responsibility of keeping your patient's prescription records confidential. Imagine the ramifications of an auditor flipping through your prescription files and discovering that their neighbor - a cash paying customer -- is receiving AZT, chlorpromazine and diazepam. What might your liability be if that

auditor went home and proceeded to tell the neighborhood about your patient?

Second, having the prescription numbers in advance enables you to pull those records to have them available for the auditors when they arrive. It's more efficient and helps save you time and effort in tracking down files and records if this can be done ahead of time.

Be aware, however, that in most cases the auditors will not want to give you the prescription numbers for fear that you could then pull these records and correct errors or improprieties. A compromise to propose is that the auditor provide the pharmacy with the majority of prescription numbers in advance and that the remaining numbers will be pulled at the time of the audit. This system speeds up the process for the pharmacist while still satisfying the auditors' concerns about "tampering."



Continued on page 23...

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facts and comparisons

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Your friends,

Joe Meyerowitz
Field Sales Manager

Allan Posner
Sales Manager

Richard Levin
Regional Vice President
Sales

Whether or not you are successful in obtaining prescription records in advance, you should insist on receiving that information.

In addition to a list of prescription records, ask what other specific information or data the auditor will require. The checklist on this page lists some of the most commonly requested items. Whether or not you are facing an audit, the time spent today in putting copies of these documents into a readily retrievable file folder is a wise investment for tomorrow.

Before you conclude your conversation with the auditor, ask how long they anticipate spending in your pharmacy. As you may wish to have additional staff on hand during the audit, this time frame will give you some idea of scheduling needs.

The Actual Audit

The bid day finally arrives and do the auditors. Before beginning the audit, ask for identification from the auditor(s) and one of their business cards for you files. Keep these along with your contract and any written communications you have received from the third-party about this or previous audits.

The first rule of conducting an audit -- one that is broken by just about every pharmacist -- is to never allow the auditor access to your records without close supervision from pharmacy personnel. Pharmacists have called MPhA after receiving a third-party audit report that requests back-payment for claims. During the course of their audits, the pharmacists allowed the auditors to look at any and all prescriptions, the auditors were able to determine that the pharmacy was not giving them the lowest price. Even though it means having additional staff on hand, and possibly tying you up for an entire day, you or another pharmacist should sit down with the auditor, extract the information they request and only that information, and personally give it to the auditor. Re

Audit Checklist

Do you have access to or know where you can find....

- ☐ Most recent copy of the third-party pharmacy contract and any plan data sheets or procedures manual sent to you from the third party?
- ☐ Third-party prescription logs, including logs for delivered prescriptions if you have delivery or mail order services?
- ☐ Pharmacy licenses and permits?
- ☐ Pharmacist licenses?
- ☐ Liability insurance policies for both the pharmacy and professional liability insurance policies for the pharmacists?
- ☐ Copies of rejected or unpaid claims from the auditing third-party as well as any documentation you may have regarding problems with the third-party's payments, processing system, etc.?

member, you have an obligation to preserve your patients prescription history confidentiality. Likewise, you also have an obligation to protect your business that could be jeopardized by an auditor on a "witch-hunt," willing to use any information in any way to recoup money for their business.

If during the course of the audit you and the auditor discover that a mistake has been made on a prescription or a claim, be sure that you record what the mistake or problem is and what explanation, if any, you give to the auditor. Bear in mind that because most third-party auditors are not familiar with Maryland's pharmacy laws and regulations, they may raise questions about how you record information.

For example, one pharmacist told the MPhA office about an auditor who wanted to deny payments for all refills previously submitted to the third-party because the pharmacist

had only recorded them in the computer and not on the back of the actual prescription. The auditor didn't believe that this was a legitimate method for documenting refills until the pharmacist was able to show that the Maryland State Board of Pharmacy considered this system acceptable. Therefore, you, as the pharmacist, should have on-hand during the audit a copy of the most current pharmacy laws and regulations.

Before the audit is concluded, make sure that you show the auditor any rejections or denied claims from the third-party. Also make sure you show the auditor any records of outstanding claims that you have not been paid for. Ask for explanations as to why the claims were rejected, denied, or why you have not received payment. Give copies of these to the auditor and ask that they be made part of his or her final report. Ask also that you receive a written copy of

the auditor's final report. Ask when you should expect the report and what appeals process is available should it become necessary.

After the Audit

Once the audit is finished, put the copies of your notes plus any material given to you by the auditor with your contract. If you do not receive the written report from the auditor you requested by the time promised, call and ask about the status of your audit. Don't be surprised if you don't hear anything -- that's generally a good sign that means everything was pretty much acceptable.

However, there are times when the audit doesn't go smoothly and the third-party expects to be reimbursed for prescriptions that they believe were inappropriately paid by them to your pharmacy.



Some third-parties use an extrapolation method to determine whether they are due money from you. Their calculations, for example, would say that since you had errors or discrepancies on ten percent of the claims audited, ten percent of the total claims submitted and paid for by the third-party must also be in error. Under no circumstances should you accept this type of audit "blackmail."

If you receive a report/bill for an amount based on audit extrapolated figures, you should refer to the notes you took during the audit. Did you have reasonable explanations for any discrepancies on prescriptions or records? What was the auditor's response to your explanations at the time of the audit? Ask for, and if necessary, demand a complete listing from the third-party of prescriptions with discrepancies and exactly what they are.

Generally, a third-party is willing to negotiate some on what they believe you owe them. At this point, and especially if their claim against you is significant, you should contact your pharmacy's attorney for assistance. Don't make the mistake of some pharmacists and just send the third-party a check without first obtaining legal advice and exhausting the third-party's appeal process.

Conclusions

Surviving a third-party audit can be relatively painless if you are properly prepared. Remember the basic rules: assert your right to have the audit conducted at a reasonable time that doesn't impose on your business nor on your patients, be honest with the auditor, never volunteer information, be familiar with Maryland's pharmacy laws and regulations, and never allow the auditor to have free access to your prescription files or records. And, if in doubt or if you need assistance, take advantage of the Maryland Pharmacists Association's resources and give us a call. **R**

New Signature Logs Provided

The National Council on Prescription Drug Programs (NCPDP) is the standard setting body for third-party programs. They were the organization who developed the Universal Claim Form and who have been implementing the criteria for electronic claim formats.

NCPDP has created a standard signature claim log for pharmacists to use in recording third-party prescription delivery to patients. With their permission, the Maryland Pharmacists Association is providing on page 25 a reproducible copy of this form for you to use.

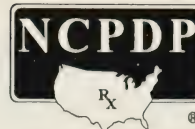
Tear page 25 out of this issue, stamp your pharmacy information in the box provided at the upper left. Keep this original form available to make copies as needed.

Audit Rules To Remember

- ▶ Never allow the auditor access to records or files that do not pertain to the third-party or its customers.
- ▶ Always request identification from the auditor before allowing them access to your records.
- ▶ Never volunteer information for which the auditor has not asked.
- ▶ Always take notes during the audit about problems or questions raised by the auditor and your explanations, if any.
- ▶ Never lie or attempt to bluff your way through an audit. If you don't have an answer to an auditor's question, tell him or her when you will have an answer and then follow through.
- ▶ Always have a copy of the Maryland pharmacy laws and regulations on hand to reference in case of questions.

(store stamp)

THIRD PARTY INSURANCE/COUNSELING CLAIM LOG
Please have the patient or legal representative who has received this prescription listed below read this statement and sign for the appropriate prescription.



STANDARD SIGNATURE CLAIM LOG

Your signature certifies you received a service or item dispensed on the date(s) listed below and that the information contained hereon is correct and that the person for whom the prescription was written is eligible for the benefits. You also certify that you have received the medication identified below and authorize release of all the information contained on this log and prescription to which it corresponds, to the plan administrator, the underwriter, the sponsor, the policyholder, the Worker's Compensation Commission (if applicable), and the employer. You hereby assign to this provider pharmacy any payment due pursuant to this transaction and authorize payment directly to this provider pharmacy.

In addition:

You understand that payment for this service or item will be from Federal and State funds and that any false claims, statements or documents, or concertment of material may be prosecuted under applicable Federal and State Laws. Furthermore, as required by State Laws you acknowledge receipt of an OFFER TO COUNSEL and have accepted or refused counseling as indicated.

WORKER'S COMPENSATION ONLY: Your signature certifies that this medication is for the treatment of an on-the-job injury.

ALL OTHER THIRD PARTY PROGRAMS: Your signature certifies that this medication is not for treatment of an on-the-job injury.

COUNSEL (R/A)	DATE DISPENSED	RX NO.	PATIENT I.D.	THIRD PARTY PROGRAM	COUNSEL (R/A)	DATE DISPENSED	RX NO.	PATIENT I.D.	THIRD PARTY PROGRAM
Signature of Patient or Legal Representative					Signature of Patient or Legal Representative				
COUNSEL (R/A)	DATE DISPENSED	RX NO.	PATIENT I.D.	THIRD PARTY PROGRAM	COUNSEL (R/A)	DATE DISPENSED	RX NO.	PATIENT I.D.	THIRD PARTY PROGRAM
Signature of Patient or Legal Representative					Signature of Patient or Legal Representative				
COUNSEL (R/A)	DATE DISPENSED	RX NO.	PATIENT I.D.	THIRD PARTY PROGRAM	COUNSEL (R/A)	DATE DISPENSED	RX NO.	PATIENT I.D.	THIRD PARTY PROGRAM
Signature of Patient or Legal Representative					Signature of Patient or Legal Representative				
COUNSEL (R/A)	DATE DISPENSED	RX NO.	PATIENT I.D.	THIRD PARTY PROGRAM	COUNSEL (R/A)	DATE DISPENSED	RX NO.	PATIENT I.D.	THIRD PARTY PROGRAM
Signature of Patient or Legal Representative					Signature of Patient or Legal Representative				

** COUNSEL (R/A)
R = REFUSED, A = ACCEPTED

No. 42

ALL UNITS ARE NOT EQUAL

A unit is a unit is a unit, right? That is exactly the misconception held by many practitioners. The Practitioners' Reporting NetworkSM (USP PRNSM) and the Institute for Safe Medication Practices, Inc. have received reports that relay health care practitioners' confusion about the accurate measurement and meaning of "units" as they relate to drug potency. The following incident represents the type of reports received:

A nurse used a 1 mL *insulin* syringe (based on a concentration of 100 units of insulin per milliliter) to administer a 25-unit dose of calcitonin injection. The nursing home staff normally uses 1 mL *tuberculin* syringes to measure the calcitonin, but the syringes were unavailable. The concentration of the calcitonin was 200 International Units per milliliter. Instead of calculating the dose in milliliters, the nurse measured the dose in units on the insulin syringe thinking that a unit of one drug is equal to a unit of another. Consequently, the patient was given double the dose, or 50 units of calcitonin.

Some of this confusion exists because practitioners may not understand that the term "unit" is not analogous to any metric measure and that there is no universal equivalency between different units. A milligram of mass is the same wherever it is measured, no matter what material is measured. A biological "unit," however, is an expression of potency that differs for each stated biological substance. A unit of activity is *not* measurable by any particular weight or volume and is the criterion against which commercial products are assayed for potency. In fact, there is no such thing as a "unit" used as a freestanding term. There is the unit for Insulin and the unit for Calcitonin, but neither of which bears any relationship to the other. In the context of food and drug regulation, "units" have no purpose other than that of a universal expression to denote an amount of a stated biological activity unique for a specified biological substance.

The need for international harmonization of biological activity measurement led to the initiation and continued development of the International Biological Standardization program, now carried out by the World Health Organization (WHO). The International (biological) Unit for any particular substance, which cannot be characterized completely by chemical and physical means, is the expression of its biological potency. The WHO establishes each particular biological preparation (the International Standard) and defines the activity contained in a specified amount of that particular preparation as the biological "unit" for that substance.

The International Standard established by WHO serves as the official worldwide reference in a biological assay. Authoritative bodies in individual countries establish their own national standard which is calibrated in terms of the International Standard. Each becomes the legal reference for the particular country. Therefore, units defined by national standards could be named to indicate their national origin (e.g., USP Units). The USP or the Food and Drug Administration define the biological activity for vitamins or antibiotics in the United States according to the quantity of a particular preparation that contains a stated amount of vitamin or antibiotic activity. Unless otherwise indicated, USP Units are equivalent to the corresponding International Units, where such exist or formerly existed.

Recent advances in chemistry and analytical techniques now make it possible to determine and define chemically the activity of many substances that previously could be quantified only biologically. When the chemical characterization or physical quantification (potency) of a substance or dosage form becomes feasible, there is no longer a need for a biological standard or for a biological unit of activity. Certain International Standards that previously used units have been discontinued because appropriate chemical and instrumental methods for their characterization have been developed. The International Unit for Vitamin A, Vitamin E, and Vitamin D were discontinued in 1954, 1956, and 1991, respectively. Nonetheless, the current label of a product that contains any of these three fat-soluble vitamins is likely to state the vitamin potency only in International Units or USP Units per capsule/tablet because of the public's familiarity with this obsolete terminology.

The use of units to measure other biological substances, like heparin, calcitonin, and insulin, can be expected to be discontinued once techniques to purify and analyze them are improved even more. Eventually, metric units would be used to express strength on product labels and in prescription orders. The process of changing label terminology may take somewhat longer in the case of insulin because of the unfamiliarity of millions of diabetics with the relevant metric equivalents.

Until the time when all USP articles are measured in metric units, informed health care practitioners must continue their diligence to educate the public that all units were not created equal.

REMEMBER: WHEN WRITING ORDERS FOR PRODUCTS THAT ARE MEASURED IN UNITS, ALWAYS WRITE OUT THE WORD "UNITS." NEVER USE THE ABBREVIATION "U"; A CARELESSLY HANDWRITTEN "U" CAN BE MISINTERPRETED AS A ZERO, LEADING TO TEN-FOLD OVERDOSES.

To report problems with drug products or to receive further information, call the USP Practitioners' Reporting NetworkSM at 1-800-4-USP PRN.

Critical Thinking & Communication Skills

Another Look at Pharmaceutical Care

Seung-Min Kim, Pharmacy Student, UMAB School of Pharmacy

This article is the eight in a series written by pharmacy students in the first course of the entry-level Pharm.D. program at the University of Maryland School of Pharmacy. PHAR 516 (Pharmacy Practice and Education) is an introductory course which exposes students to pharmacy practice, pharmaceutical sciences, ethics, communication, and critical thinking. One of the class assignments was to write a critical evaluation on one of three topics: pharmaceutical care, pharmacy technicians, or mail-order pharmacy. This course was developed by MPhA Past President Ilene Zuckerman with the assistance of graduate student Diane McNalley.

One mid afternoon, a physician you know well calls and presents a problem he has with one of his patients, Bill Blinton, a forty-six year old male. He has been prescribed to take medication for his stand-up-hairditis. The doctor seems very concerned with Mr. Blinton's condition becoming worse and believes it could be caused by adverse drug reactions. Mr. Blinton has been instructed to visit you and the doctor asks for your input in this situation. Before Mr. Blinton arrives, you quickly look up the disease, understand the course of its action, and review his medical records.

When he arrives, you immediately establish a patient-pharmacist relationship with Mr. Blinton and gather relevant information about his problem and medication. He tells you that he is only on one medication, a lotion to soften his hair. After having read the description of the disease and obtaining proper data, you realize that Mr. Blinton has not had an adequate amount of treatment and the next step in treating this disease is the start of another drug, Anti-Worry capsules. Once you have identified the drug-related problem and have chosen the best pharmacotherapeutic solution, you set a time when he should return or a number you can call to monitor the outcomes of the drug. You have the responsibility to make sure the solution brings about the desired outcome and note any undesirable effects of the drug. After the completion of the treatment, you keep a record of the problem and the solution and make a documentation of this case.

This above scenario has just described the definition and the process of pharmaceutical care. Although the concept of pharmaceutical care has obtained a great deal of attention, the implementation of this concept into practice has not occurred. The main reason for this is the lack of pharmaceutical care knowledge. Pharmacy practitioners as well as the public are not familiar with this concept, therefore appropriate planning and possible consequences of this program will enable pharmacists to engage in it and allow the patients to gain trust for the pharmacists and the program. However, before planning anything, the public and the pharmacists must understand the term pharmaceutical care.

This term was newly defined by Hepler and Strand in the Keystone Address to the October 1989 Pharmacy in the 21st Century conference as the "responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life." Pharmaceutical care is viewed as a health care need in which the pharmacist is held responsible for the outcomes of drug therapy. These outcomes may be the cure of a disease. Pharmaceutical care is more patient-focused than program focused and acknowledges all settings where the patient may be treated. Therefore, the continuity of care from one setting to another is another important basis for this program. The overall goal of the program is to keep patients at the highest possible level of wellness through the best management of drug therapy.

Now that pharmaceutical care has been defined, some practical questions must be raised about the actual operation of the systematic process before planning to implement this into practice settings. Such questions are: what specific changes must occur in the way pharmacist practice in order to practice pharmaceutical care? How much time is required for each patient and how many patients can be cared for by each pharmacist? How will the continuity of care be monitored and ensured? And what problems and barriers would pharmacists face?

The importance of good communication skills among pharmacists in different settings in order to ensure the continuity of patient care should be noted. As for the amount of time required and the number of patients a pharmacist can care for, a three-week trial program was conducted by the University of California-San Diego Medical Center. They concluded the average time needed for a patient work-up to be approximately 30 minutes and patient monitoring to be 15 minutes per patient per day. Each pharmacist was able to establish relationships with 25 to 30 patients. They also noted that substantial amount of time was devoted to "drug delivery problems, purchasing problems and other types of problems that could have been handled by technical personnel and others on the staff." In short, they realized the importance of changing the way pharmacists practice, changing the roles and responsibilities of technician and relying more on computers.

It is imperative that a pharmacist deeply considers these qualifications and requirements in order to successfully implement pharmaceutical care into the standard of pharmaceutical practice. And the promotion of this plan involves these following major changes in pharmacy practice: 1) developing a support system for the professional practice pharmacist. The roles of pharmacy technicians should be redefined to take on the greatest level of responsibility that can be safely done by them. A pharmacist will begin to accept the systematic process of pharmaceutical care when there is widespread training and use of technicians; 2) Improvement of the computer system for communication and documentation is also of great importance.

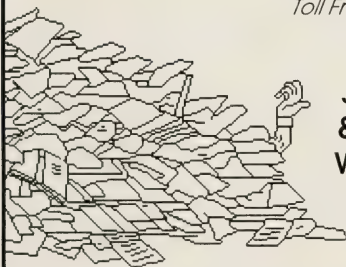
Speaking of documentation, this aspect of the plan should be essential and be required by professionals. Because of the lack of documentation, the proposed pharmaceutical care program is not recognized as basic patient care service and so the importance of pharmaceutical care to society is not apparent. And there must be enough documentation before widespread reimbursement for pharmaceutical care will occur. Therefore, without adequate documentation, the value of pharmaceutical care can be assessed and reimbursement for this professional service will not take place. If these changes do occur, an easier environment will be created for pharmacists to make pharmaceutical care a standard practice.

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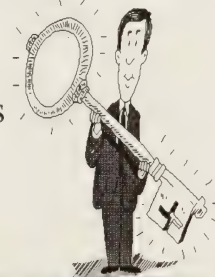
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Continuing Education

Continuing Education Quiz

November 1994 -- Dandruff/Seborrhea

This month's questions are taken from the article on recently introduced drug therapies for AIDS that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members \$10.00). The completed quiz for this issue must be received by May 31, 1995. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

Social Security Number _____

Address _____

City/State/ZIP Code _____

1. Which of the following is a true statement?
 - a. Dandruff scales are dry, seborrheic scales are greasy.
 - b. Dandruff scales are greasy, seborrheic scales are dry.
 - c. Both dandruff and seborrheic scales are dry.
 - d. Both dandruff and seborrheic scales are greasy.
2. All of the following are indicated for treating both dandruff and seborrhea *except*:
 - a. coal tar
 - b. retinoic acid
 - c. selenium sulfide
 - d. zinc pyrithione
3. The large lumps of cells that shed off the scalp in dandruff are called?
 - a. eczema
 - b. plaque
 - c. squamiae
 - d. psoriasis
4. The most common cause of cradle cap is:
 - a. a surge of hormone production
 - b. excessively slow formation of keratin cells
 - c. improper washing of the affected area
 - d. an allergic reaction to detergents
5. Selenium sulfide and zinc pyrithione are classified in which of the following therapeutic groups?
 - a. keratolytic
 - b. antimicrobial
 - c. cytostatic
 - d. antipruritic
6. Dandruff and seborrhea occur when the shedding rate of keratin cell is:
 - a. nonexistent
 - b. excessive
 - c. stagnant
 - d. insufficient
7. Dandruff and seborrhea are similar in that they both:
 - a. onset at puberty.
 - b. cause greasy scales.
 - c. produce inflammation and redness.
 - d. only occur on the scalp.
8. Patients with seborrhea should seek professional assistance in all of the following situations *except*:
 - a. when it is on the eyelids
 - b. when it does not improve within several weeks of using a medicated shampoo.
 - c. when it occurs on children under two years.
 - d. when it occurs on the scalp.
9. The organism whose concentration on the affected area is depressed in persons with seborrhea is:
 - a. *Candida albicans*
 - b. *Pityrosporum ovale*
 - c. *Staphylococcus aureus*
 - d. *Propionibacterium acnes*
10. All of the following statements about skin cells are correct *except*:
 - a. they are formed continually in the epidermis.
 - b. they divide by mitosis.
 - c. they migrate upward toward the skin's surface.
 - d. they die and become hydrated.

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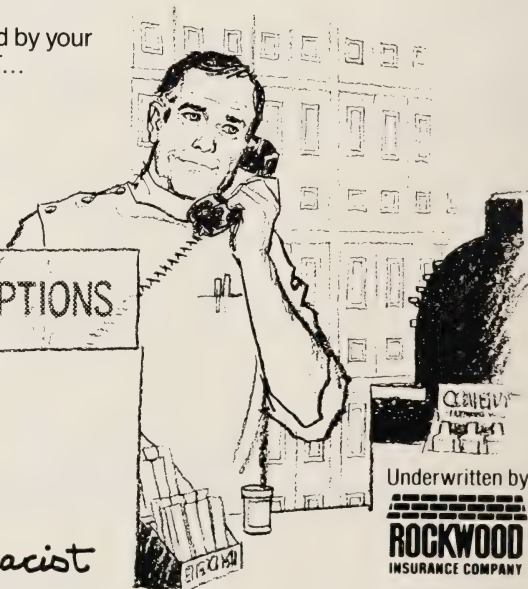
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The Maryland Pharmacist

VOL. 70

December, 1994

NO. 12



*Seasons
Greetings!*



Finding the Right Balance

The 1995 MPhA Mid-Year Educational Meeting

Sunday, February 26, 1995

Loews Annapolis Hotel, Annapolis, Maryland

Program

- 8:00 am Arrivals, Registration and Continental Breakfast
- 9:00 am *Continuing Education Seminar*
**Your Duty to Warn:
Pharmacists Legal Liability**
Gerald Mazzucca
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- 10:30 am *Continuing Education Seminar*
New Drugs and Drug Therapies I
Robert Kerr, Pharm.D.
David Roffman, Pharm.D.
SPONSORED BY MERCK
- 12:30 noon Luncheon
- 1:30 pm *Professionwide Business Session*
**Board of Pharmacy Nominee
Presentations**
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- 2:30 pm *Continuing Education Seminar*
New Drugs and Drug Therapies II
- 4:00 pm *MPhA House of Delegates Session*

Registration

Early registration for this program is \$50 for MPhA members (\$60 for non-members) if received by MPhA by February 1, 1995. Thereafter, registration prices increase to \$60 for members (\$70 for non-members). To register for the 1995 MPhA Mid-Year Meeting, complete and detach the accompanying registration form. Return the form with payment (check or money order or credit card information) to the MPhA offices. For further information or questions, contact MPhA at (410) 727-0746 or (800) 833-7587.

This program will provide attendees with 5 hours of continuing education credits. The MPhA Mid-Year Meeting is made possible through the generous sponsorship of the following companies: Astra/Merck, Boots, Searle, SmithKline Beecham, Merck, Miles, Pfizer, Schering, Ortho Pharmaceuticals, Apoteco.

Learning Objectives

At the conclusion of this program, the attendee will be able to:

- Describe the impact of recent court decisions against pharmacists as it pertains to increase professional responsibility.
- List three strategies that pharmacists can take to reduce their risk of liability and increase pharmaceutical care to patients.
- Compare new drugs with previously available agents.

1995 MPhA Mid-Year Meeting

February 26, 1995

Loews Annapolis Hotel

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The Maryland Pharmacist

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650 West Lombard Street, Baltimore, Maryland 21201-1572

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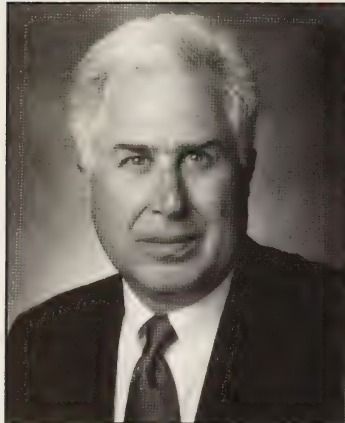
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President's Commentary

Arnold Davidov, P.D., 1994-1995 MPhA President



If for no other reason at all, comedian Rodney Dangerfield will be forever enshrined in American pop culture for coining the phrase, "I get no respect." And let's not forget Queen of Soul Aretha Franklin's admonition, "R-E-S-P-E-C-T. Find out what it means to me!"

Pharmacists have a lot to be proud of when it comes to respect. The 1994 Gallup Poll has again placed us at the top of the list of the annual rating of trusted professionals. Sixty-two percent of 1,000 randomly selected Americans rated the category "Druggists/pharmacists" as high or very high when asked how they would rate the honesty and ethical standards of various occupations. This year, we've even widened our gain on the clergy, who ranked second at 54 percent. Bringing up the bottom of the list were Senators, insurance salesmen, Congressmen, and car salesmen.

For six straight years, pharmacists are at the top of the Gallup poll. Yet, it is my belief that pharmacists and many of the people they deal with show almost no respect for this fine profession. I specifically mean the seemingly constant infighting between pharmacists themselves (eg. academics vs. practitioners, Pharm.D. vs. B.S., independents vs. chains, consultants vs. long term care vendors, etc., etc.). As President of MPhA, I see and feel this lack of respect among my colleagues all too often. And, I must admit I get caught up in it as well.

Frankly, it's so easy to show *dis*respect and often so hard to show respect -- especially when your own views, beliefs and values differ from those of another pharmacist. The habit of disrespect is practically effortless when you consider the treatment of all pharmacists at the hands of pharmacy benefit management companies, third-party administrators, politicians and others. After all, why not beat up on somebody else when you're being beaten on by someone else.

At this time of year, it's traditional to look back on the past year, think about what you did well, what you could have done better, what you want to do in the future. If I have one wish for the profession in 1995, it's that each of us will treat the other with the same respect and hold each other in the same esteem that American consumers feel for us.

R

New Drugs in 1994 -- Part II

Antibiotics and Antifungal Agents

Thomas A. Gossel, R.Ph., Ph.D., Dean, Ohio Northern University

J. Richard Wuest, Pharm.D., Professor of Pharmacy Practice, University of Cincinnati



This lesson reviews the new antibiotics: cefepime (Maxipime), cefpodoxime (Vantin) and piperacillin/Tazobactam (Zosyn), and the antifungal itraconazole (Sporanox). Dosage forms and regimens for these drugs are listed in Table 1.

The "1P" designation noted after the name of the drug signifies that it was given priority approval by FDA because the drug represented a significant advantage over previously available therapy. The "1S" notation means the drug went through the standard approval process.

Antibiotics

Two cephalosporins and an extended spectrum penicillin derivative were approved for marketing since our last review of new drugs. At the time of writing this lesson, the total number of cephalosporins marketed in the U.S. had risen to 24. Several others have been approved but not marketed.

This makes the cephalosporins the most widely prescribed of all antibiotic groups. A major reason for their popularity is the broad spectrum of bacteria susceptible to them, and their relatively low incidence of side effects.

All three of these antibiotics act in the same manner as other cephalosporins and penicillin derivatives. They inhibit transpeptidase activity and, therefore, prevent proper peptide incorporation into the developing new cell wall as susceptible organisms reproduce. This damages the ability of these bacteria to maintain an

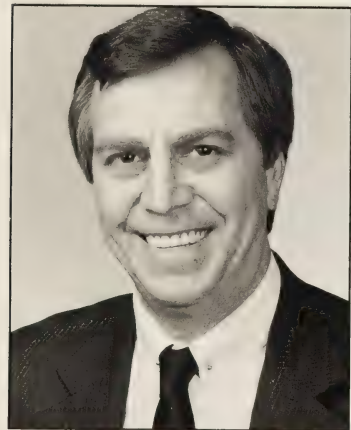
osmotic barrier against the fluids surrounding them. Water rushes through the defective cell wall as the bacteria are cloning their next generation, causing them to swell and burst. Therefore, they are bactericidal antibiotics.

Cephalosporins

Cephalosporins are divided into three classes or generations based primarily on their pharmacokinetics and spectrum of action. While all of the drugs in this class have the same mechanism of action, they differ in their ability to penetrate various organisms. We will use the first, second and third generation classifications, but point out that there are so many cephalosporins on the market that the differentiation between categories is getting fuzzier and fuzzier.

First generation cephalosporins are effective against many Gram-positive and several Gram-negative bacteria. Examples include cefadroxil (Duracef) and cephalexin (Keflex). These are ideal for community-acquired infections in ambulatory patients, and mild to moderate infections in institutionalized patients.

Second generation cephalosporins have greater activity against Gram-negative organisms including cefaclor (Ceclor), Cefmetazole (Zinacef) and cefoxitin (Mefoxin). Their greatest use for respiratory and urinary tract infections in hospitalized patients and in children with otitis media.



This educational program is made possible through a grant-in-aid from

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Third generation cephalosporins have even greater Gram-negative activity. This group includes cefixime (Suprax), ceftazidime (Fortaz, Tazicef and Tazidime), and ceftriaxone (Rocephin). They were initially targeted for hospital-acquired infections.

However, their long half-life and their effectiveness against *Hemophilus influenzae*, which has become resistant to other antibiotics, has led to their use in ambulatory patients, especially children.

A case in point is a child with a middle ear infection who is well enough to go to school, but needs several days of therapy to eradicate the infection. Many schools do not allow the administration of medications to students. The advantage of giving the dose before or after school is obvious.

Cefepime-Maxipime (1S)

Cefepime is a third generation cephalosporin. Its spectrum includes *Pseudomonas*. It has been useful in treating respiratory tract, skin and soft tissue and urinary tract infections.

Claims have been made that it should be classified as a "fourth generation" cephalosporin since its activity against *pseudomonas* is as good as any other cephalosporin, and it has good stability to betalactamases. Also, it is effective against organisms resistant to other third generation agents, and it has improved action against Gram-positive organisms as compared to other third generation cephalosporins.

This may eventually be of importance because generally, as cephalosporins gain activity against Gram-negative organisms, they lose some Gram-positive effectiveness. However, cefepime is not effective against methicillin-resistant staphylococci and has poor activity against anaerobic bacteria.

Cefpodoxime - Vantin (1S)

Vantin is available in its proxitel ester form. this enhances absorption

New Antibiotics and Antifungal Agents

Generic Name	Trade Name	Availability	Dosage Regimen
Cefepime	Maxipime	1 & 2 gram vials	1 to 2 grams every 12 hours IM or IV
Cefpodoxime	Vantin	100 & 200 mg tablets; 50 & 100mg/5 ml suspension	100 to 200 mg every 12 hours with food for 7 to 12 days
Piperacillin/Tazobactam	Zosyn	2.25, 3.375 & 4.5 gram vials	3.375 grams every 6 hours by IV infusion
Itraconazole	Sporanox	100 mg capsules	200 mg once daily with food

Table 1

significantly. As such, it is the precursor (prodrug) to its active moiety. This means that, after absorption from the gastrointestinal tract, the ester is converted to its active metabolite- cefpodoxime.

It has a relatively long half-life and resistance to destruction by betalactamases. Thus, it joins Suprax, Cefzil and Lorabid in the treatment of respiratory, skin and soft tissue and urinary tract infections involving betalactamase producing bacteria.

While most cephalosporins can be taken either with food or on an empty stomach, its manufacturer states that Vantin should be taken with food to improve absorption. Information useful in counseling patients taking Vantin is presented in Table 2.

Piperacillin/Tazobactam - Zosyn (1S)

Zosyn is a combination of piperacillin (an extended spectrum penicillin-derivative available for several years) and tazobactam (a newly released betalactamase inhibitor) in an 8 to 1 ratio. The 2,3, and 4 gram vials of piperacillin contain 225, 375 and 450 mg tazobactam respectively, and are expressed as 4.225, 3.3375 and 4.450 grams. They are available as lyophilized powders which are to be reconstituted with dextrose 5 percent in water or normal saline

solution.

Piperacillin is the fourth penicillin derivative to be marketed in combination with a beta-lactamase inhibitor after amoxicillin, ampicillin and ticarcillin. Tazobactam is the third beta-lactamase to be used in this country. Clavulanate and sulbactam preceded it.

All three of the beta-lactamase inhibitors are simple structure derivatives of penicillanic acid that have no intrinsic antibacterial action. They are referred to as "suicidal enzyme inhibitors" because when they combine with beta-lactamases, they modify and inactivate them. This spares the antibiotic and restores its original spectrum of activity.

It should be pointed out that the production of beta-lactamase enzymes is a major contributor to the development of resistance by bacteria against penicillins and cephalosporins. These enzymes are able to hydrolyze penicillins and cephalosporins when the antibiotics enter previously susceptible bacteria.

After being hydrolyzed, the antibiotic is not able to bind with the intracellular bacterial enzyme systems that synthesize the cell wall of developing progeny. This renders the antibiotic ineffective and makes the bacteria resistant to penicillin or cephalosporin derivatives.

Piperacillin by itself is most often

used in combination with an aminoglycoside antibiotic to treat patients with hospital-acquired pneumonia -- concurrently in the same patient, but not mixed in the same intravenous infusion. They are therapeutically synergistic but chemically incompatible.

Therapeutic Uses

Zosyn is ticketed for use in the initial treatment of patients with serious multi-microbial infections. This type of therapy is used to cover the patient with a broad spectrum antibiotic until the infective organism(s) and agent of choice for treatment are identified.

When used in combination with piperacillin, tazobactam extends its spectrum to beta lactamase producing bacteria including several strains of *E. coli*, *Klebsiella*, *Clostridia*, *Proetus*, *Providencia*, *Bacteroides*, and *Enterobacter*. While it also decreases the

effective dose of other penicillins and cephalosporins, tazobactam's combination with piperacillin is more active against beta-lactamase producing Gram-negative bacilli.

Zosyn enters the market at a difficult time for new, expensive drugs. In the current era of "cost containment" there is resistance to adding new, potentially more expensive drugs to the formularies in many hospitals. The target infective conditions for Zosyn are moderate to severe piperacillin-resistant infections that have been categorized into four groups:

- appendicitis complicated by rupture or abscess and peritonitis;
- uncomplicated and complicated skin and soft tissue infections and ischemic/diabetic foot infections;
- postpartum endometritis and pelvic inflammatory disease; and,
- moderate to severe community acquired pneumonia.

According to the *Medical Letter* consultants (Vol. 36, #914, 1/21/94), the standard treatment for infections that are likely to involve anaerobes includes either clindamycin or metronidazole together with an aminoglycoside, or alternately, ticarcillin/clavulanate (Timentin), ampicillin/sulbactam (Unasyn), imipenem (Primaxin), cefoxitin (Mefoxin), or cefotetan (Cefotan).

For treatment of community acquired bacterial pneumonia when the organism is unknown, cefuroxime (Kefurox or Zinacef) is widely used, sometimes with erythromycin added to cover *Legionella*, *Chlamydia*, and *Mycoplasma*. Trimethoprim-sulfamethoxazole, third-generation cephalosporins and beta-lactam/beta-lactamase inhibitor combinations are also used.

The conclusion of the *Medical Letter* consultants is that clinical studies have generally shown no

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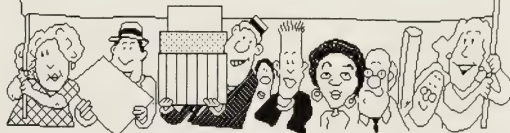


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important differences in effectiveness among these regimens. Therefore, the marketer of Zosyn will have to convince hospital Pharmacy and Therapeutics Committees of the worthiness of this product.

Adverse effects to piperacillin/tazobactam reported at the five percent or great level are diarrhea (11 percent), constipation (8 percent), headache (8 percent) nausea (7 percent) and insomnia (7 percent). However the report that listed these did not compare them to a placebo group so their significance is unknown.

One possible advantage of piperacillin/tazobactam over other beta-lactam/beta-lactamase inhibitor combinations is the situation where sodium content is important, such as in cardiac patients. Zosyn contains only one-half the sodium of Timentin and Unisyn -- 2.35 mEq per gram versus 4.75 mEq and 5 mEq per gram for the other two products.

Zosyn is to be reconstituted with a small amount (approximately 5 ml) of D5W or NSS, further diluted with the same IV fluid and infused over a 30 minute period.

Antifungal Agent - Itraconazole

Itraconazole is an orally active systemic triazole antifungal agent. It joins ketoconazole (Nizoral) and fluconazole (Diflucan) in this category. Itraconazole is claimed to have a wider spectrum of activity and greater potency than the previously available oral triazole antifungals.

It is effective against the dermatophytic (attack dead tissue such as skin, hair and nails) fungi including *Microspora* and *Trichophyton* species that cause ringworm infections. And, it is effective against the mycotic (deep seated, systemic) fungi such as *Blastomyces*, *Histoplasma* and *Aspergillus* species. Itraconazole is also effective against the yeast-like fungi including *Candida* and *Cryptococci* species.

The mechanism of action of the

three oral triazole antifungal agents is basically the same. They enter susceptible fungi and prevent the synthesis of ergosterol. This substance is the building block for fungal cell membranes. Ergosterol is

to plants as cholesterol is to animals. Inhibition of ergosterol prevents formation of the next generation of fungi. At usual therapeutic doses, itraconazole is fungistatic.

Itraconazole was given priority

Patient Counseling for Vantin

Vantin is used to treat infections

- ▶ To maximize the absorption and to reduce the chance of stomach upset, Vantin should be taken with food. For the liquid form, the contents should be shaken well just before measuring the dose. There are special measuring devices available. If you want one, ask one of our pharmacists.
- ▶ The recommended length of treatment with Vantin is usually 7 to 10 days. All of the medicine dispensed should be taken unless otherwise instructed by your doctor.
- ▶ If you or your child experience diarrhea while taking Vantin, *do not* take any antidiarrheal medicine without first asking your doctor or pharmacist.
- ▶ If a dose of Vantin is missed, it should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosage schedule. *Do not* take or give a double dose unless your doctor has instructed otherwise.
- ▶ Keep the tablets at room temperature in their original, labeled container. Store the liquid in the refrigerator.
- ▶ *Do not* keep or use outdated medicine. Be sure the liquid medicine is in good date before using it.
- ▶ Keep this and all medicine out of the reach of children.
- ▶ In case of accidental ingestion or overdose, call your doctor or poison control center immediately.

Every medicine is capable of producing side effects. Most patients experience little or no problem while taking their medicine. However, be sure to tell your doctor if the following occur while you or your child are taking Vantin: skin rash, hives, itching, shortness of breath or wheezing, swelling of the face, prolonged nausea, vomiting or diarrhea, persistent sore throat or fever, or any other unusual, bothersome effects.

(Adopted from the Pharmex PALS (patient advisory leaflets). For more information, call (800) 233-0585.)

Table 2

1994 Recipients of the "Bowl of Hygeia" Award



Wyeth-Ayerst Laboratories takes great pride in continuing the "Bowl of Hygeia" Award Program developed by the A. H. Robins Company to recognize pharmacists across the nation for outstanding service to their communities. Selected through their respective professional pharmacy associations, each of these dedicated individuals has made uniquely personal contributions to a strong, healthy community and richly deserves both congratulations and our thanks for their high example.

Patient Advice for Sporanox

Sporanox is used to treat fungal infections

- ▶ To maximize absorption and to reduce the chance of stomach upset, the capsules should be taken with food.
- ▶ Long-term therapy with Sporanox is sometimes needed (possibly 3 months or longer). It is important to take the full length of treatment unless otherwise instructed by your doctor.
- ▶ DO NOT change the amount of Sporanox taken or stop taking it without consulting your doctor.
- ▶ While the occurrence is rare, you may experience dizziness, blurred vision or drowsiness from Sporanox. If you do, be careful driving or performing hazardous tasks. Alcoholic beverages can increase drowsiness.
- ▶ You should talk with your doctor before taking the following prescription medicines with Sporanox: astemizole (Hismanal) and terfenadine (Seldane, Seldane-D).
- ▶ If you miss a dose of Sporanox, take it as soon as possible. But, if it is almost time for your next dose, skip the missed capsule and go back to your regular schedule. *Do not* take a double dose, unless your doctor has instructed you otherwise.
- ▶ *Do not* keep or use outdated medicine.
- ▶ Keep Sporanox at room temperature, in its original, labeled container and out of the reach of children.
- ▶ In case of accidental ingestion or overdose, call your doctor or poison control center immediately.

Every medicine is capable of producing side effects. Most patients experience little or no problems while taking their medicine. However, be sure to tell your doctor if the following occur while taking Sporanox: dizziness, drowsiness or confusion, nausea or vomiting, stomach pain, severe headache, diarrhea, yellowing of the skin or eyes, loss of appetite, dark or amber colored urine or any other unusual, bothersome effects.

Table 3

consideration in its approval process because it is useful in treating AIDS patients. Although there were already two antifungals in its class available commercially, the number of fungal infections in the country continues to rise. One estimate places the number of cases of blastomycosis and histoplasmosis between 3,000 and 5,000 per year,

with most of the affected patients being HIV positive.

The activity of the triazole antifungals is due to an ability to inhibit the cytochrome P-450 (CP450) enzyme system. This group of enzymes is also referred to as the mixed function oxidase enzyme system. A large group of these enzymes (over 50 -- they are more

properly called isozymes since they are part of the whole group) have been found in nature but not all species utilized the same isozymes. A case in point is that the CP450 isozyme subset used by fungi are different than those used by humans.

This is why the triazoles are antifungal with little effect on human cells. They have more selectivity to the CP450 isozymes used by fungi and are unlikely to inhibit human CP450 isozymes used in synthesizing cholesterol. However, this differentiation is not so strong for drug metabolism in humans as will be discussed shortly under drug interactions for itraconazole.

The adverse effects of itraconazole relate mostly to the G.I. tract with nausea reported in 11 percent of patients studied and vomiting at 5 percent. Rash (9 percent) is the other adverse effect reported at the 5 percent or greater level.

One very rare (3 patients out of 2500 studied), but important, adverse effect is hepatitis. The package insert for itraconazole advises patients to report any signs of liver dysfunction (i.e., loss of appetite, persistent nausea/vomiting, unusual tiredness, pale stools, darkened urine or yellow coloration of the skin) to their doctor, who in turn is advised to discontinue the drug.

One adverse effect for ketoconazole that has not been seen with itraconazole in therapeutic doses is suppression of cortisol or testosterone production.

Drug Interactions

There is evidence that ketoconazole (Nizoral) can interfere with terfenadine (Seldane) and astemizole (Hismanal) metabolism resulting in higher blood levels of these two antihistamines. Manufacturers of Seldane and Hismanal state that they should not be given concurrently. Their package inserts have a boxed warning about the possibility of cardiac arrhythmias when taken in overdose, and that

systemic antifungals (including itraconazole) can increase their potential to do this. The warning states that concurrent use is contraindicated.

The significance of an interaction between itraconazole and terfenadine and astemizole is not clear-cut. There has been a lot of press and discussion about the potential for an interaction between erythromycin, which is also a CP450 inhibitor, a ketoconazole with these two non-sedating antihistamines.

However, if one looks closely at the reports, one finds that most articles are reviews of what others have published. This means they are interpretations of interpretations rather than hard evidence that there truly is a significant problem.

Ketoconazole and itraconazole inhibit the CP450 isozyme system. While this does not significantly affect the normal oxidative reactions in humans, it can reduce the metabolism of drugs administered to humans, including terfenadine and astemizole.

In the instance of itraconazole, one could argue that it was not available when the retrospective review of non-sedating antihistamines was published, so, how could it possibly have been involved in an interaction? The answer to this appears to be because it is a close structural relative of ketoconazole. In the scientific world of pharmacology and pharmacokinetics, this is certainly not proof of significance. However, the world of politics, the lay press and the current legal system are another matter.

Setting aside opinions, the current "truth" is that the package inserts for Seldane and Hismanal contain "boxed" warnings that contraindicate the concurrent use of itraconazole. Therefore, they should not be administered to the same patient.

At this point in time, loratidine (Claritin) has not been shown to cause the same problems and it might be a safer alternative. While CP450 inhibitors can reduce loratidine metabolism, there is not evidence at

this time that this increases cardiac arrhythmias.

Patient Advice

Long-term therapy with itraconazole is needed, possibly for months, so compliance is important. Its absorption is greatly enhanced by low gastric pH and the presence of food in the stomach. Therefore, patients should be advised to take the dosage with food.

To enhance absorption, Sporanox capsules are specially formulated. The itraconazole is dispersed in a hydrophilic polymer of hydroxypropyl methylcellulose which is coated on the surface of beads with an inactive core of sucrose and starch. On swallowing, after the hard gelatin capsule dissolves, this formulation allows for rapid release and dispersion of the itraconazole, thus enhancing its absorption.

Information useful in counseling patients taking Sporanox is presented in Table 3.

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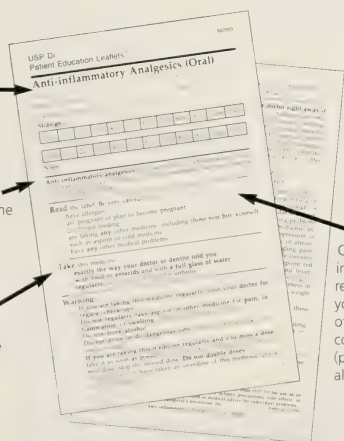
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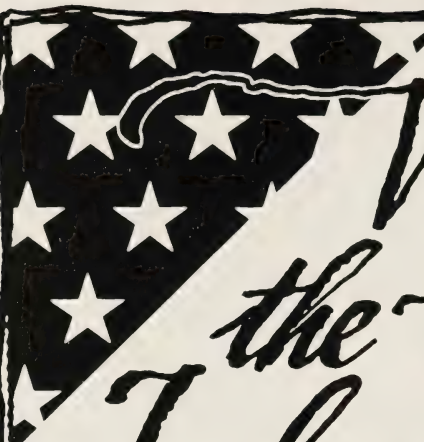
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Continuing Education Quiz

December 1994 -- New Anti-infectives

This month's questions are taken from the article on recently introduced drug therapies for anti-infectives that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members \$10.00). The completed quiz for this issue must be received by June 30, 1995. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

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1. Zosyn is a combination of piperacillin and:
 - a. clavulanate.
 - b. penicillamine.
 - c. sulbactam.
 - d. tazobactam.
2. The ingredient in Zosyn referred to in question one above is added to piperacillin to:
 - a. increase its absorption from the G.I. tract.
 - b. protect it from destruction by betalactamases.
 - c. decrease its metabolism in the liver.
 - d. prevent it from causing liver damage.
3. Cephalosporins and penicillins prevent proper cell wall development because they inhibit bacterial:
 - a. transpeptidase.
 - b. DNA polymerase.
 - c. reverse transcriptidase.
 - d. cytochrome P-450 isozymes.
4. Cefepime is classified as a:
 - a. first generation cephalosporin.
 - b. second generation cephalosporin.
 - c. third generation cephalosporin.
 - d. extended spectrum penicillin.
5. The spectrum of activity of Vantin is *least* similar to:
 - a. Cefzil.
 - b. Keflex.
 - c. Lorabid.
 - d. Suprax.
6. Which of the following antihistamines is *least* likely to interact significantly with itraconazole?
 - a. Claritin
 - b. Hismanal
 - c. Seldane
7. Patients receiving Sporanox should be advised:
 - a. to avoid excessive exposure to sunlight.
 - b. to store the prescription container in the refrigerator.
 - c. that the medicine discolors urine.
 - d. to take the dose with food.
8. All of the following points of information are correct when counseling patients taking Vantin *except*:
 - a. finish all doses prescribed, even if you feel better after only a few doses.
 - b. take each dose on an empty stomach, at least two hours either side of food.
 - c. if diarrhea occurs while taking Vantin, call your doctor or pharmacist before self-medicating with an OTC antidiarrheal.
 - d. store the liquid form of Vantin in a refrigerator and shake the container well before measuring each dose.
9. Sporanox prevents proper cell wall function by inhibiting fungal:
 - a. transpeptidase.
 - b. DNA polymerase.
 - c. reverse transcriptidase.
 - d. cytochrome P-450 isozymes.
10. Which of the following would be the most effective drug for oral treatment of an infection caused by a beta-lactamase producing bacteria?
 - a. Maxipime
 - b. Sporanox
 - c. Vantin
 - d. Zosyn

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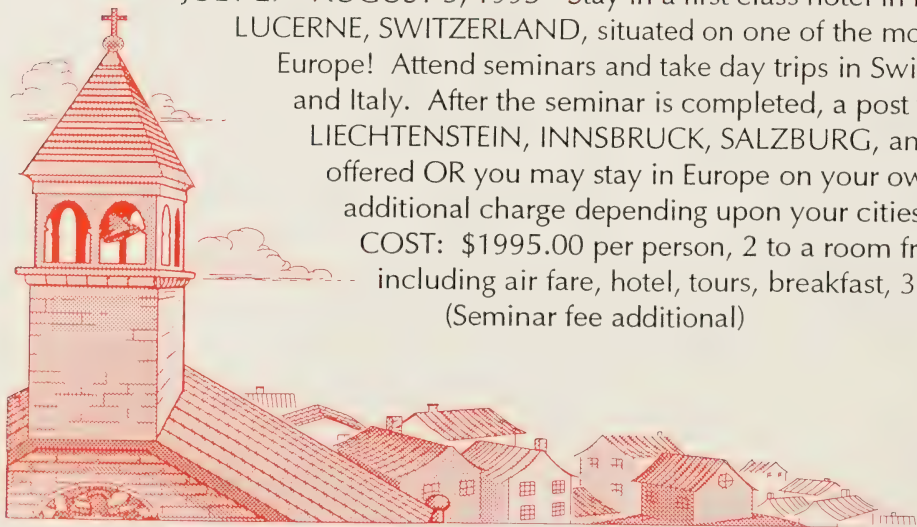


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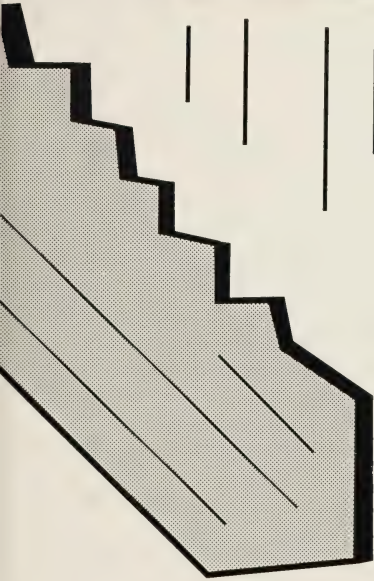
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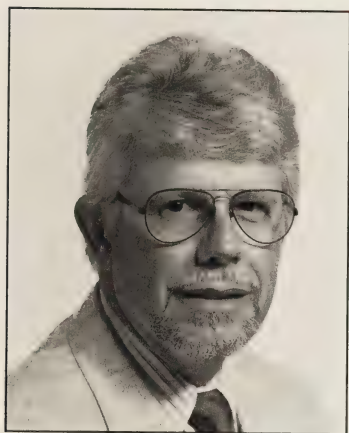
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Pharmacy in Finland

A Visit to the Land of the Midnight Sun

Richard D. Baylis, P.D.



It's 10:00 am and still dark outside. I am about 500 miles south of the Arctic Circle in Turku, Finland. It's December 21, winter solstice, and the shortest day of the year. Very shortly, the sun will begin to peek over the horizon and stay in that position until about 3:30 pm, when dusk returns. A local physician advises me that there are several pharmacies in the city and he will introduce me to the pharmacists working in them.

The first pharmacy (*apoteeki*) I visited is owned by the immediate past-president of the Finnish Pharmaceutical Society.

The second pharmacy, Turun Kauppatorin Apoteeki, is very old. It was started in 1689 and has never closed its doors. The current owner is H.T. Turakka. Dr. Turakka is a former professor of pharmacy at the University. They have been at the present location, on the city square, since 1866. Prior to that, they were on the waterfront, in the Old Town. This area was destroyed by a city-wide fire. Much of the original interior is still intact, but some has been removed by previous owners to save as collectibles.

The pharmacy exudes an old world charm while still keeping up to pace with modernity. The pharmacists, all women except for the owner and manager, attend to the patients' needs from behind a low counter. The whole operation is computer controlled. The patients even have an interactive computer on which to ask questions about their medications. The patient information is obtained from the USP-DI and translated into

Finnish.

This pharmacy has many house brand items for sale as OTC's. They actually are manufactured on the premises. They even compound hydrogen peroxide in the upstairs laboratory. The technicians were preparing headache powders when I visited the lab. They have an analytical chemist on the staff to maintain the quality controls required by the government.



Some OTC's come from the United States. A saliva alcohol test kit called "QED A 150" was offered for sale for about 45 Finnish Marks (\$9.00 US). The kit was manufactured by Enzymatics, Inc. of Horsham, Pennsylvania. I noticed a tube of Clearasil on the shelf made in the USA. Carafate and ibuprofen 400mg are available over-the-counter. Carafate is called Alsucral and is made by Orion.

Durable medical equipment is sold in separate shops. Some are even associated with optometrists. Cosmetics are sold in separate shops also. Home infusion care is not offered by Finnish pharmacies. All infusion services are done through hospital services.

Pharmacists undergo rigorous training at the Finnish University. There are several levels of pharmacy degrees offered. First there is the *Farmaseutti*. These are assistant pharmacists with 3 years training -- one year of classroom instruction and 2 years of practical experience. There are there is *Proviisori*. They attend school for five more years and receive the equivalent of a Master of Science degree, requiring a thesis and research project for graduation. Thirdly there are the *Lisensiaatti*. These pharmacists present a doctoral dissertation and receive a degree equivalent to a Ph.D. in America. And fourthly, there are *Doctors* degrees. This degree requires even more schooling. All store owners must be licensed pharmacists.

Unlike many other European countries, Finland has no government limit on the number and location of pharmacies. This is controlled strictly by the market.

Pharmacists work eight hours a day, five days a week. The pharmacies are open 5 days per week. Every six weeks, a pharmacy may be open for seven days per week, depending on a rotated schedule

developed amongst the pharmacies in each municipal area.

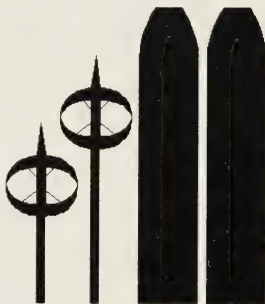
Health insurance is guaranteed to all Finns through payroll taxes. The Social Security system covers the costs of medicines, medical care, hospitalization, and dentistry. The pharmacy benefit pays 40% of the total prescription cost with a 45 Mark (\$9 US) deductible or patient copayment. The benefit was 50% until 1992 when it was lowered because of budget restraints. The patient pays an additional tax on the prescription (Value Added Tax - VAT), of 22%. The pharmacy pays an annual pre-

scription tax based upon the number of prescriptions dispensed in a year. This tax amounts to about 20% over and above the usual business income taxes.

Their Social Security drug benefit covers specific chronic diseases at a higher rate of reimbursement. Medicines for glaucoma, epilepsy, cancer, Parkinsonism and diabetes are covered at 100% rate; therapies for hypertension, cardiac insufficiency, hypercholesteremia, asthma are covered at an 80% rate.

The government is experimenting with "smart cards" for prescription filling records. The prescription is written by the physician and the pharmacist records the dispensing information on the card for future refills. The prescription is canceled and a notation of filling is made on the reverse side. Unlike the U.S., the patient keeps the actual written prescription. The "smart cards" are an experiment to do away with the paper trail.

In Turku there is a pharmacy museum. It is owned and maintained by the city government. The building is 350 years old and contains a complete pharmacy circa 1600 and housing for the apothecary. **R**

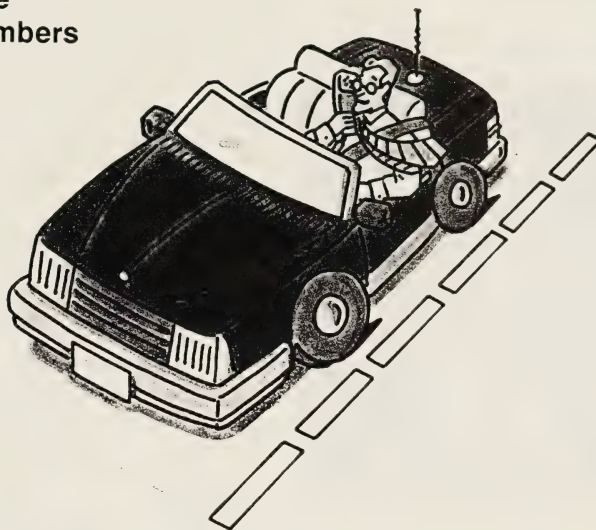


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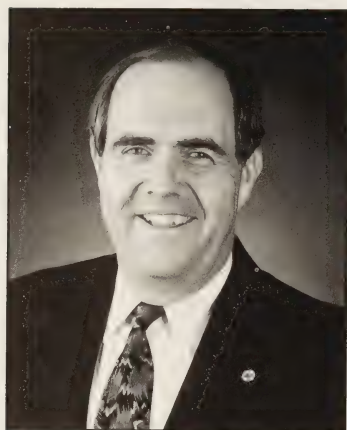
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Pharmaceutical Care Benefit Principles

A Professionwide Activity to Assure Patient Protection

John Gans, Pharm.D., Executive Vice President, American Pharmaceutical Association



The Board of Trustees of the American Pharmaceutical Association have announced the development of a health industry-wide set of "Pharmaceutical Care Benefit Principles" to further advance the value of pharmacists in the delivery of pharmaceutical care. These principles will serve as the benchmark by which pharmacy benefit programs are measured in the marketplace.

Our organization has recognized that it is central for the health of the patients we serve that pharmaceutical care become a truly integrated and adequately remunerated benefit in the managed health care system. We have shifted from a strategy of endorsing specific benefit management programs to one which promotes these essential components or principles necessary for acceptable pharmaceutical benefit plan design.

Our vision is that all pharmaceutical care benefit plans include the following components:

- ▶ recognize the value of the patient and pharmacist relationship.
- ▶ support the provision of pharmaceutical care through adequate compensation in conjunction with appropriate recognition of the pharmacist's role in therapy management.
- ▶ include professional support systems and educational materials which facilitate the pharmacists'

role in achieving optimal therapy outcomes.

- ▶ include remuneration based on sound, scientifically defensible methodology.
- ▶ utilize technology that integrates health information and reflects current national standards, and
- ▶ provide for ongoing outcomes evaluation and documentation.

APhA invites all pharmacists to share their comments and suggestions on these principles. Written comments should be directed to Mitchel Rothholz, R.Ph., Director, State Services, American Pharmaceutical Association, 2215 Constitution Avenue, NW, Washington, DC 20037.



Principle 1

The Pharmaceutical Care Benefit Program recognizes the value of the patient/pharmacist relationship.

- a. The Pharmaceutical Care Benefit Program permits any pharmacy provider willing to meet specified service quality, delivery and financial requirements of a plan to participate in serving patients under that plan.
- b. Within the limits specified above, the Pharmaceutical Care Benefit Program 1) assures the patients have convenient access to prescription drug therapy and professional pharmacy services from the pharmacy of their choice and 2) avoids unreasonable administrative, distribution channel or financial plan

- requirements which create unnecessary access barriers.
- c. The Pharmaceutical Care Benefit Program encourages the patient's use of the most cost effective prescription drug therapy and professional pharmacy services through reasonable administrative rules and financial incentives that are evenly applied to all participating providers.

Principle II

The Pharmaceutical Care Benefit Program supports the provision of pharmaceutical care.

- a. The Pharmaceutical Care Benefit Program uses compensation systems that encourage pharmacy providers to select the most cost effective pharmaceutical products and to provide professional services to assure optimum patient drug therapy outcomes.
- b. The Pharmaceutical Care Benefit Program provides for pharmacist/prescriber communication which reinforces the pharmacist's role as patient advocate by assisting prescribers in the selection of optimum cost effective therapy.
- c. The Pharmaceutical Care Benefit Program encourages pharmacist review, continuous oversight and implementation of consensually recognized supportive care strategies aimed at patient adherence to the physician's therapy goals in order to improve health outcomes.
- d. The Pharmaceutical Care Benefit Program encourages patients, prescribers, and pharmacists to openly, actively and regularly communicate about the anticipated effects, potential side effects, and actual experiences associated with drug use.
- e. The Pharmaceutical Care Benefit Program provides financial incentives for interactive pharmacist/patient drug therapy review and counseling which, at a minimum, occurs with all new medication prescriptions, first refills of new medicines, and at reasonable maintenance medication review periods.

Principle III

The Pharmaceutical Care Benefit Program provides support systems and materials to pharmacists and beneficiaries and facilitate their roles in achieving optimum therapy outcomes.

- a. The Pharmaceutical Care Benefit Program provides clear, well-articulated materials to beneficiaries and providers. Full and accurate disclosure of plan design and implementation is incorporated in these materials.
- b. The Pharmaceutical Care Benefit Program provides timely notification and educational materials relating to program enhancements to pharmacy providers and plan beneficiaries.
- c. The Pharmaceutical Care Benefit Program compensation systems for pharmaceutical products and professional pharmacy services provide timely notice of financial incentives that help pharmacists identify appropriate dispensing and service processes and behaviors.



Principle IV

The Pharmaceutical Care Benefit Program remuneration to pharmacy providers should be based on sound, defensible methodology.

- a. The Pharmaceutical Care Benefit Program rewards quality professional service delivery by pharmacists through compensation systems and reporting mechanisms which are identifiably separate and distinct from compensation for product and for distribution.
- b. The Pharmaceutical Care Benefit Program provides product cost reimbursement mechanisms that assure that no single provider obtains financial arrangements that disadvantage another class of trade.

Principle V

The Pharmaceutical Care Benefit Program administration utilizes technology that integrates health information and reflects current national standards.

- a. The Pharmaceutical Care Benefit Program makes use of an automated point of service processing system which is compliant with national standards, specifically standardization in areas such as prospective DUR and professional service coding requirements.
- b. Pharmacists should be able to validate the patient's participation in a Pharmaceutical Care Benefit Program and assure appropriate allocation of benefit liabilities, either electronically or otherwise.
- c. The Pharmaceutical Care Benefit Program's ID cards include all information needed to successfully adjudicate claims.
- d. Programs assure prompt electronic payment of claims.

Principle VI

The Pharmaceutical Care Benefit Program provides for ongoing program evaluation and documentation.

- a. The Pharmaceutical Care Benefit Program uses reporting systems which regularly disseminate relevant information to pharmacy providers in order to allow providers to enhance their dispensing and pharmaceutical care systems (i.e., drug therapy statistics; therapy guidelines; feedback on individual prescriber and dispensing pharmacist behaviors related to prescribing and patient utilization efficiencies; and relative performance on DUR related alerts, therapy interventions and patient outcomes).
- b. The Pharmaceutical Care Benefit Program utilizes pharmacist/practitioner involvement in The Pharmaceutical Care Benefit Program design, operations oversight and ongoing evaluation.

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Litigation Update

Duty to Refuse Prescriptions

David B. Brushwood, R.Ph., J.D.



The Supreme Court of Indiana has recently vacated an opinion of the Court of Appeals of Indiana, in which the Court of Appeals had ruled that a pharmacist could have no duty to refuse a prescription if the pharmacist had called the prescriber and received verification that the prescription was valid. The ruling reinstates a trial court denial of dismissal of the defendant pharmacy and pharmacists from the lawsuit. The case will proceed against the pharmacy and pharmacists.

The court described the facts of the case as overuse of propoxyphene by a patient who suffered from back pain. The patient was consuming the drug at a rate much faster than prescribed. For example, during one 66-day period the patient received 24 separate refills of propoxyphene, totalling 1,072 dosage units. If consumed according to the directions in the prescription, the drug should have lasted for 138 days; but the patient had used them in 62 days.

When the prescriber became aware that the patient was consuming the drug at a rate much faster than prescribed, he refused to prescribe the drug. The patient suffered suicidal tendencies that required medical treatment. The patient sued the pharmacy and two pharmacists on the theory that they had breached their duty of care by failing to stop filling the prescriptions when they knew or should have known that the patient was consuming the drugs so frequently that they posed a threat to his health.

The court held that a pharmacist has a duty of care under such circumstances. The court stated as follows:

"It is a matter of common expectation as well as statute that pharmacists possess expertise regarding the dispensing of prescription drugs. It is a matter of common understanding that customers rely upon pharmacists for that expertise. Upon this basis, we conclude that the relationship between a pharmacist and customer is sufficiently close to justify imposing a duty."

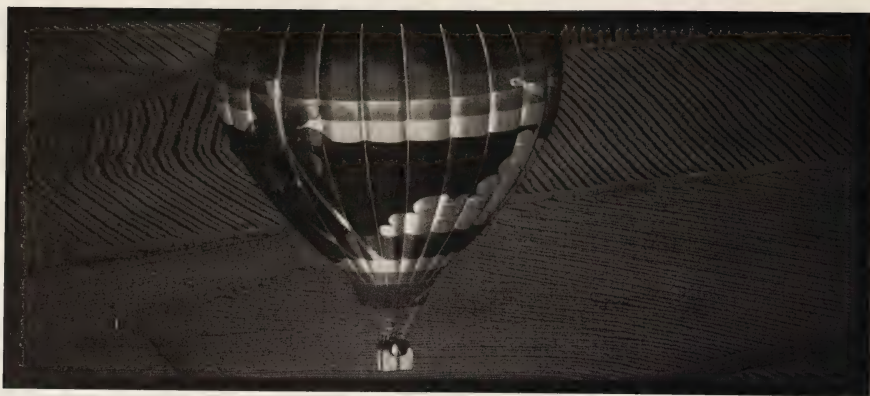
The court rejected arguments that such a duty would create an adversarial relationship between pharmacists and physicians. In fact, the court said: "We believe recognition of a legal duty will encourage pharmacists and physicians to work together in considering the best interests of their customers and patients."

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Based on: *Hooks SuperRx, Inc. v. McLaughlin*, 1994 Westlaw 619709, Ind. November 10, 1994) Copyright 1994, David B. Brushwood. All Rights Reserved. Reprinted From *Dickinson's Pharmacy*, December 1994.

About the Author

David Brushwood is Professor of Pharmacy Health Care Administration at the University of Florida. His articles on cases affecting pharmacies and pharmacy are provided as a courtesy to state pharmacist associations. Questions on legal issues affecting Maryland practice should be directed to your legal representative or the Maryland State Board of Pharmacy.



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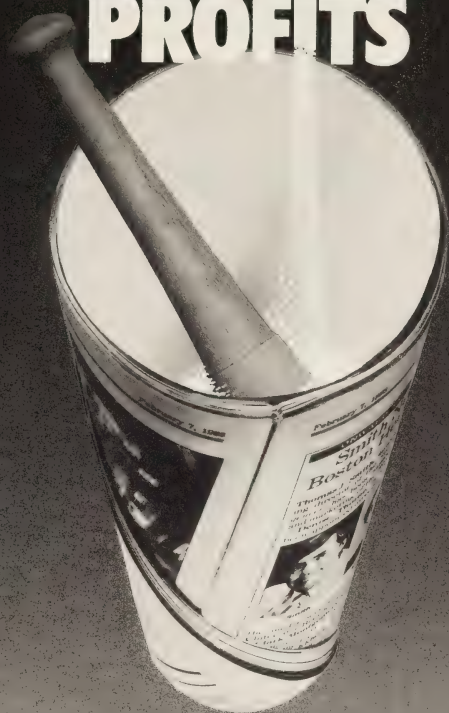
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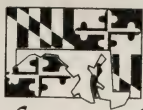
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EASY BREATHING

Have you, as a practitioner, ever wondered if your patients are relaying accurately their experiences with inhalers? Are you unsure whether or not the inhaler is being used correctly? Are you exasperated when patients say they only got 100 sprays instead of the labeled 200 doses, that it tastes funny this time, or that they're not getting the expected relief?

Experimental work on albuterol metered-dose inhalers by the Canadian Health Protection Branch (CHPB) (the equivalent of the U.S. Food and Drug Administration) shows that the amount of drug in a dose from this metered-dose inhaler (MDI) product depends on how much time has lapsed since the preceding dose and the position in which the MDI has been stored. This study found that the drug content of single sprays of albuterol MDI ranged between 23% and 208% of the label claim. Additional evidence from this study suggests that initial sprays from a new canister had a higher drug content than the final doses emitted from that same canister. Single, unprimed doses (doses taken 4 or more hours following the last spray) from individual canisters stored with the valve in the upright position and activated after 4 or 16 hours averaged a higher drug content than single, unprimed doses from canisters stored with the valve down. Primed sprays (i.e., those sprays that were taken within minutes of a previous spray), whether stored with the valve up or the valve down, contained a mean of 92% of labeled drug content. These results are reflected in reports received through the USP Practitioners' Reporting NetworkSM (USP PRNSM) in the accompanying table.

Another study by the CHPB examined cromolyn sodium metered-dose inhalers. The results of this study indicated that many of the doses tested were consistently outside USP dosage uniformity limits. The amount of active ingredient contained in the doses tested varied between each canister and also varied within individual canisters tested.

The May–June 1994 *Pharmacopeial Forum* (PF) contains two *Stimuli* articles from the USP Advisory Panel on Aerosols suggesting improvements in standards that specifically address new aerosol products and continuing problems with aerosols. Redrafts of two mandatory USP general tests chapters, *Aerosols* (601) and *Uniformity of Dosage Units* (905), have been recommended. The redrafts formulate new tests, modify existing ones, and then designate those tests that are specific only to pressurized aerosols intended for topical application, metered-dose inhalers, or dry powder inhalers. In addition, the panel recommends renaming the chapter *Aerosols* (601) to *Aerosols, Metered-dose Inhalers, and Dry Powder Inhalers* (601).

While the Advisory Panel recommendations address changing the physical characteristics of aerosol dosage delivery, one Panel member recommends the addition of a supplementary test to chapter (601) entitled *Dose Uniformity Over the Entire Contents*. Lack of uniform therapeutic delivery is a real concern to patients and was cited also in the CHPB study. The author of this latest article, which appears in the May–June 1994 PF, recommends that inhalers be tested for drug content per dose using dose collection schedules that imitate how patients actually use the product.

The Advisory Panel is seeking comments and suggestions prior to making its final recommendations, which would be subject to review, revision, and acceptance by the USP Subcommittee on Excipients prior to being added to USP-NF. Once new requirements are adopted and made official, all manufactured aerosol products would be required to conform.

In the meantime, health care practitioners can help ensure the proper use and proper storage of inhalers by counseling patients appropriately. Proper storage of inhalers in an upright position should be emphasized, especially if the patient's scheduled dose is a single, unprimed spray. Storage at the proper temperature is also important. For example, carrying an aerosol canister in a purse, pocket, backpack, suitcase, or storing the canister in the glove compartment of a car during the summer could expose the product to compromising temperatures. Storage of the inhaler in a prone position may result in a less than effective dose. An unusual taste may indicate that the inhaler is delivering nonactive ingredients, such as propellants in a concentration other than that expected.

While counseling the patient, it should be recommended that the inhaler system be primed if any significant length of time elapses between doses. The next dose of a medication to be delivered to a patient is actually contained in a reservoir. Priming will ensure that a full dose is contained in the reservoir so the patient will not be underdosed.

Finally, thorough counseling should reveal if the patient understands the information in the patient package insert and if the patient is using the product correctly. Additional counseling at the time of refill may be necessary in order to reinforce proper inhalation techniques, handling, and storage.

The following incidents were reported through the USP PRN between April 1993 and May 1994. The abstracted information represents problems and complaints experienced with inhalers.

Table of DPPR Reports on Inhalers

Inhaler	Reported Incident
<i>Albuterol inhaler</i>	The aerosol mechanism does not work properly and continues to discharge the product. The container does not deliver a uniform amount of medication. The container does not hold the labeled number of doses, or it feels empty before any usage. The latest refill is not therapeutically effective. The valve on a full canister will not activate.
<i>Beclomethasone dipropionate inhaler</i>	Only 20 inhalations are emitted from a container that should deliver 200 inhalations. There was one complaint about getting only two doses from each of the past two canisters before the inhaler quits working. The mechanism does not work properly and continues to discharge medication, even after pressure is removed from the valve, emptying the container. Two actuations are required per dose; the second actuation does not always work.
<i>Metaproterenol sulfate inhaler</i>	The latest refill does not provide any therapeutic effect and tastes "fishy." The latest refill is therapeutically ineffective.
<i>Terbutaline sulfate inhaler</i>	There are two instances of a metallic taste in mouth, burning in lungs, and worsening of asthma symptoms while using the product. The condition improves upon replacement of inhaler. The last two refills do not provide the labeled number of doses.
<i>Flunisolide inhaler</i>	Two different canisters, dispensed one right after the other, do not contain the labeled number of doses. In another case, the latest refills deliver only 19 and 68 respective doses; this is an ongoing problem. The inhaler is reported to deliver a super-potent dose.
<i>Pirbuterol acetate inhaler</i>	The inhaler works sporadically and is not reliable.
<i>Nedocromil sodium inhaler</i>	The device malfunctions and sprays mist inside the chamber instead of via the valve to the patient.
<i>Triamcinolone acetonide inhaler</i>	The device needs to be actuated twice in order to get one inhalation.
<i>Ipratropium bromide inhaler</i>	The device delivers medication inconsistently; medication loses its effectiveness after 10 days of regular use. The device delivers only 100 of the labeled 200 inhalations.

To report similar problems with drug products or to receive further information, call the USP Practitioners' Reporting NetworkSM at 1-800-4-USP PRN.

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